

ATTACHMENT 3

CENTRAL PROCESSING REGULATIONS

NABP MODEL RULES

Section 3. Pharmacy Practice.

A. Prescription Drug Order

A Prescription Drug Order shall contain the following information at a minimum:

- (1) full name and street address of the patient;
- (2) name, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;
- (3) date of issuance;
- (4) name, strength, dosage form, and quantity of Drug prescribed;
- (5) directions for use;
- (6) refills authorized, if any;
- (7) if a written Prescription Drug Order, prescribing Practitioner's signature;
- (8) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;
- (9) if a hard copy Prescription Drug Order generated from electronic media, prescribing Practitioner's electronic or manual signature. For those with electronic signatures, such Prescription Drug Orders shall be applied to paper that utilizes security features that will ensure the Prescription Drug Order is not subject to any form of copying and/or alteration.

B. Manner of Issuance of a Prescription Drug Order

A Prescription Drug Order, to be effective, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice.

- (1) A Prescription Drug Order must be communicated directly to a Pharmacist, or when recorded in such a way that the Pharmacist may review the Prescription Drug Order as transmitted, to a Certified Pharmacy Technician, in a licensed Pharmacy. This may be accomplished in one of the following ways. A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in written form. A Prescription Drug Order, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) or by way of Electronic Transmission.
- (2) If communicated orally or by way of Electronic Transmission, the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist or Certified Pharmacy Technician that may be maintained for the time required by laws or rules.
- (3) A Prescription Drug Order for a Schedule II controlled substance may be communicated orally and/or by way of Electronic Transmission only in the following situations and/or with the following restrictions. Otherwise, a Prescription Drug Order for a Schedule II controlled substance must be communicated in written form.
 - (a) A Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner or the Practitioner's agent by way of Electronic Transmission, provided the original written, signed Prescription Drug Order is presented to the Pharmacist for review prior to the actual Dispensing of the controlled substance, except as noted in paragraph (b) or (c) of this Section 3.B.(3). The original,

written Prescription Drug Order shall be maintained in accordance with Section 3.F. (Patient Records).

- (b) A Prescription Drug Order for a Schedule II narcotic substance to be Compounded for the direct Administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be communicated by the Practitioner or the Practitioner's agent to the Home Infusion Pharmacy by way of Electronic Transmission. The hard copy of such Electronic Transmission serves as the original, written Prescription Drug Order for purposes of this Section 3.B.(3)(b), and it shall be maintained in accordance with Section 3.F. (Patient Records).
- (c) A Prescription Drug Order for a Schedule II controlled substance for a resident of a Long-Term Care Facility may be communicated by the Practitioner or the Practitioner's agent by way of Electronic Transmission. The hard copy of such Electronic Transmission serves as the original, written Prescription Drug Order for purposes of this Section 3.B.(3)(c), and it shall be maintained in accordance with Section 3.F. (Patient Records).
- (d) In the case of an Emergency Situation, a Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner orally or by way of Electronic Transmission, provided that:
 - (i) The quantity prescribed and Dispensed is limited to the amount adequate to treat the patient during the emergency period (Dispensing beyond the emergency period must be pursuant to a written Prescription Drug Order signed by the prescribing Practitioner);
 - (ii) The orally communicated Prescription Drug Order shall be immediately reduced to writing by the Pharmacist or Certified Pharmacy Technician, or, if necessary, the Prescription Drug Order communicated by way of Electronic Transmission shall be immediately reduced to a hard copy, and either shall contain the information required by Section 3.A. (Prescription Drug Order);
 - (iii) If the prescribing Practitioner is not known to the Pharmacist or Certified Pharmacy Technician, he must make a reasonable effort to determine that the oral authorization came from a registered Practitioner, which may include a callback to the Practitioner using the Practitioner's phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and
 - (iv) Within 7 days after authorizing an emergency oral Prescription Drug Order, the Practitioner shall cause a written Prescription Drug Order for the emergency quantity prescribed to be delivered to the Dispensing Pharmacist. In addition to conforming to the requirements of Section 3.A, the Prescription Drug order shall have written on its face "Authorization for Emergency Dispensing," and the date of the orally or electronically transmitted Prescription Drug Order. The written Prescription Drug Order may be delivered to the Pharmacist in Person or by mail, but if delivered by mail, it must be postmarked within the 7-day period. Upon receipt, the Dispensing Pharmacist shall attach this written Prescription Drug Order to the emergency oral Prescription Drug Order, which had earlier been reduced to writing, or to the hard copy of the electronically transmitted Prescription Drug Order. The Pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration if the prescribing Practitioner fails to deliver a written Prescription Drug Order.

- (4) All Prescription Drug Orders communicated by way of Electronic Transmission shall:

- (a) be transmitted directly to a Pharmacist or Certified Pharmacy Technician in a licensed Pharmacy of the patient's choice with no intervening Person having access to the Prescription Drug Order;
 - (b) identify the transmitter's phone number or any other suitable means to contact the transmitter for verbal and/or written confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law;
 - (c) be transmitted by an authorized Practitioner or his designated agent; and
 - (d) be deemed the original Prescription Drug Order, provided it meets the requirements of this subsection.
- (5) The prescribing Practitioner may authorize his agent to communicate a Prescription Drug Order orally or by way of Electronic Transmission to a Pharmacist or Certified Pharmacy Technician in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order.
- (6) The Pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the Prescription Drug Order communicated by way of Electronic Transmission consistent with existing Federal or State laws and rules.
- (7) All electronic equipment for receipt of Prescription Drug Orders communicated by way of Electronic Transmission shall be maintained so as to ensure against unauthorized access.
- (8) Persons other than those bound by a confidentiality agreement pursuant to Section 2.A. (2)(k) shall not have access to Pharmacy records containing Protected Health Information concerning the Pharmacy's patients.

C. Transfer of a Prescription Drug Order

Pharmacies utilizing automated data processing systems shall satisfy all information requirements of a manual mode for Prescription Drug Order transferral, except as noted in subsection (4) below. The transfer of original Prescription Drug Order information for the purpose of refill Dispensing is permissible between Pharmacies subject to the following requirements:

- (1) The information is communicated directly between Pharmacists or Certified Pharmacy Technicians and the transferring Pharmacist or Certified Pharmacy Technician records the following information:
- (a) Write the word "VOID" on the face of the invalidated Prescription Drug Order;
 - (b) Record on the reverse side of the invalidated Prescription Drug Order the name and address of the Pharmacy to which it was transferred and the name of the Pharmacist or Certified Pharmacy Technician receiving the Prescription Drug Order;
 - (c) Record the date of the transfer and the name of the Pharmacist or Certified Pharmacy Technician transferring the information; and
 - (d) The computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above.
- (2) The Pharmacist or Certified Pharmacy Technician receiving the transferred Prescription Drug Order information shall reduce to writing the following:
- (a) Write the word "TRANSFER" on the face of the transferred Prescription Drug Order.

- (b) Provide all information required to be on a Prescription Drug Order pursuant to State and Federal laws and rules, and include:
 - (i) date of issuance of original Prescription Drug Order;
 - (ii) original number of refills authorized on original Prescription Drug Order;
 - (iii) date of original Dispensing;
 - (iv) number of valid refills remaining and date of last refill;
 - (v) Pharmacy's name, address, and original prescription number from which the Prescription Drug Order information was transferred; and
 - (vi) name of transferring Pharmacist or Certified Pharmacy Technician.
- (c) Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of Pharmaceutical Care.
- (3) Both the original and transferred Prescription Drug Order shall be maintained for a period of five years from the date of last refill.
- (4) Pharmacies accessing a common electronic file or database used to maintain required Dispensing information are not required to transfer Prescription Drug Orders or information for Dispensing purposes between or among Pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each Prescription Drug Order and refill Dispensed, and, further, that a hard copy record of each Prescription Drug Order transferred or accessed for purposes of refilling shall be generated and maintained at the Pharmacy refilling the Prescription Drug Order or to which the Prescription Drug Order is transferred and shall protect against the illegal use or disclosure of Protected Health Information.
- (5) In an emergency, a Pharmacy may transfer original Prescription Drug Order information for a non-controlled substance to a second Pharmacy for the purpose of Dispensing up to a 72-hour supply without voiding the original Prescription Drug Order.

D. Drug Product Selection by the Pharmacist

- (1) A Pharmacist Dispensing a Prescription Drug Order for a Drug product prescribed by its brand name may select any Equivalent Drug Product provided that the Manufacturer or Distributor holds, if applicable, either an approved New Drug Application (NDA) or an approved Abbreviated New Drug Application (ANDA), unless other approval by law or from the Federal Food and Drug Administration is required.
- (2) The Pharmacist shall not select an Equivalent Drug Product if the Practitioner instructs otherwise, either orally or in writing, on the Prescription Drug Order.
- (3) The Pharmacist shall notify the patient or patient's agent if a Drug other than the brand name Drug prescribed is Dispensed.
- (4) Whenever Drug product selection is performed by a Pharmacist, the Pharmacist shall Dispense the Equivalent Drug Product in a container Labeled in accordance with Section 3.E (Labeling).

E. Labeling

- (1) All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements:

- (a) The label of a single-unit package of an individual-dose or unit-dose system of packaging of Drugs shall include:
 - (i) the non-proprietary or proprietary name of the Drug;
 - (ii) the route of Administration, if other than oral;
 - (iii) the strength and volume, where appropriate, expressed in the metric system whenever possible;
 - (iv) the control number and expiration date;
 - (v) identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label; and
 - (vi) special storage conditions, if required.
- (b) When a multiple-dose Drug Distribution system is utilized, including Dispensing of single unit packages, the Drugs shall be Dispensed in a container to which is affixed a label containing the following information:
 - (i) identification of the Dispensing Pharmacy;
 - (ii) the patient's name;
 - (iii) the date of Dispensing;
 - (iv) the non-proprietary and/or proprietary name of the Drug Dispensed; and
 - (v) the strength, expressed in the metric system whenever possible.
- (2) All Drugs Dispensed to inpatients for self-Administration shall be Labeled in accordance with Subparagraph 4 of this Section E.
- (3) Whenever any Drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:
 - (a) name of solution, lot number, and volume of solution;
 - (b) patient's name;
 - (c) infusion rate;
 - (d) bottle sequence number or other system control number;
 - (e) name and quantity of each additive;
 - (f) date of preparation;
 - (g) Beyond-Use Date and time of parenteral admixture; and
 - (h) ancillary precaution labels.
- (4) All Drugs Dispensed to ambulatory or outpatients shall contain a label affixed to the container in which such Drug is Dispensed including:
 - (a) the name and address of the Pharmacy Dispensing the Drug;
 - (b) the name of the patient for whom the Drug is prescribed; or, if the patient is an animal, the name of the owner and the species of the animal;
 - (c) the name of the prescribing Practitioner;
 - (d) such directions as may be stated on the Prescription Drug Order;
 - (e) the date of Dispensing;

- (f) any cautions which may be required by Federal or State law;
- (g) the serial number of the Prescription Drug Order;
- (h) the name or initials of the Dispensing Pharmacist;
- (i) the proprietary or generic name of the Drug Dispensed and its strength, if more than one strength of the Drug is marketed;
- (i) When Dispensing an Equivalent Drug Product, the word "INTERCHANGE" or letters "IC" must appear on the label affixed to the container in which such Drug is Dispensed, followed by the generic name and Manufacturer, or reasonable abbreviation, and/or Distributor of the chosen product.
- (ii) The requirements of (i) only apply to single-entity, multiple-source Drugs.
- (iii) When Dispensing a single-entity, single-source Drug, the trade name of the prescribed Drug may also appear on the label, and the generic name of the prescribed Drug may also appear on the label.
- (iv) When Dispensing a fixed combination product, the United States Pharmacopeia's publication of Pharmacy Equivalent Names (PEN) for fixed combination products is the official list of abbreviations for such Labeling, and will be the approved abbreviation for identifying the combination product Dispensed. If no PEN has been officially issued by the USP, the Practitioner or Pharmacist will label the medication secundum artem.
- (v) Subsections (i) - (iv) apply in all cases of Dispensing by Practitioners or Pharmacists.
- (j) the name of the Manufacturer or Distributor of the Drug;
- (k) the Beyond-Use Date.
- (l) All Drugs Dispensed to a patient that have been filled via a Centralized Prescription Processing System shall bear a label containing an identifiable code that provides a complete audit trail of the Dispensing of the Drug and Pharmaceutical Care activities.
- (5) No radiopharmaceutical may be Dispensed unless a label is affixed to the immediate container bearing the following information:
 - (a) the standard radiation symbol;
 - (b) the words "Caution – Radioactive Material"; and
 - (c) the prescription number.
- (6) No radiopharmaceutical may be Dispensed unless a label is affixed to the outer or Delivery container bearing the following information:
 - (a) the standard radiation symbol;
 - (b) the words "Caution – Radioactive Material";
 - (c) the radionuclide and chemical form;
 - (d) the activity and date and time of assay;
 - (e) the volume, if in liquid form;
 - (f) the requested activity and the calibrated activity;
 - (g) the prescription number;

- (h) patient name or space for patient name. Where the patient's name is not available at the time of Dispensing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after Dispensing the radiopharmaceutical, the patient's name shall become a part of the Prescription Drug Order to be retained for a period of three years;
- (i) the name and address of the nuclear Pharmacy;
- (j) the name of the Practitioner; and
- (k) the lot number of the prescription.

F. Patient Records

- (1) A patient record system shall be maintained by all Pharmacies for patients for whom Prescription Drug Orders are Dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously Dispensed Drugs at the time a Prescription Drug Order is presented for Dispensing, and be created and stored in a manner to protect against illegal use or disclosure of Protected Health Information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:
 - (a) full name of the patient for whom the Drug is intended;
 - (b) street address and telephone number of the patient;
 - (c) patient's age or date of birth;
 - (d) patient's gender;
 - (e) a list of all Prescription Drug Orders obtained by the patient at the Pharmacy maintaining the patient record during the (number) years immediately preceding the most recent entry showing the name of the Drug, prescription number, name and strength of the Drug, the quantity and date received, and the name of the Practitioner; and
 - (f) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.
- (2) The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, Drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs or Devices currently being used by the patient which may relate to Prospective Drug Review.
- (3) A patient record shall be maintained for a period of not less than five years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.
- (4) Protected Health Information may be used or disclosed as allowed under Section 4 of this regulation.

G. Prospective Drug Regimen Review

A Pharmacist shall review the patient record and each Prescription Drug Order presented for Dispensing for purposes of promoting therapeutic appropriateness by identifying:

- (1) over-utilization or under-utilization;
- (2) therapeutic duplication;

- (3) Drug-disease contraindications;
- (4) Drug-Drug interactions;
- (5) incorrect Drug dosage or duration of Drug treatment;
- (6) Drug-allergy interactions; and
- (7) clinical abuse/misuse.

Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

H. Patient Counseling

- (1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:
 - (a) the name and description of the Drug;
 - (b) the dosage form, dose, route of Administration, and duration of Drug therapy;
 - (c) intended use of the Drug and expected action;
 - (d) special directions and precautions for preparation, Administration, and use by the patient;
 - (e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 - (f) techniques for self-monitoring Drug therapy;
 - (g) proper storage;
 - (h) prescription refill information;
 - (i) action to be taken in the event of a missed dose; and
 - (j) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.
- (2) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.
- (3) A Pharmacist providing Telepharmacy services across state lines shall:
 - (a) identify himself or herself to patients as a "licensed Pharmacist;"
 - (b) notify patients of the jurisdiction in which he or she is currently licensed to Practice Pharmacy and registered to Practice Telepharmacy across state lines; and
 - (c) provide patients with that jurisdiction's Board of Pharmacy address and/or phone number.
- (4) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).
- (5) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or

caregiver refuses such consultation.

I. Continuous Quality Improvement Program

- (1) Each Pharmacy shall establish a Continuous Quality Improvement Program. As a component of its Continuous Quality Improvement Program, each Pharmacy shall assure that periodic meetings are held by staff members of the Pharmacy to consider the effects on quality of the Pharmacy system due to staffing levels, workflow, and technological support. Such meetings shall review data showing evidence of the quality of care for patients served by the Pharmacy and shall develop plans for improvements in the system of Pharmacy Practice so as to increase good outcomes for patients. Incidents of medication errors shall be reported to an error reporting program designated by the Board. For those Persons utilizing a Drug formulary, a periodic review of such formulary shall be undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.
- (2) **Criteria and Standards**
Each Pharmacy shall adopt Criteria and Standards that reflect the benchmark against which the Pharmacy intends to measure itself over a designated period of time. The adopted Criteria and Standards shall be sufficiently specific to permit comparisons of quality from one period of time to another. The adopted Criteria and Standards shall be sufficiently broad to permit a self-assessment of the quality of Pharmaceutical Care provided by the Pharmacy to the patients served by the Pharmacy.
- (3) **Localized Minimum Data Set**
Each Pharmacy shall maintain a Localized Minimum Data Set of data related to patients for whom the Pharmacy provides pharmaceutical products and services so as to permit a determination as to whether Criteria and Standards have been met at the Pharmacy over time. The data shall be maintained in such a way that comparisons between actual performance and Criteria and Standards for performance can be routinely done.
- (4) **Periodic Self-audit**
Each Pharmacy shall conduct a Periodic Self-audit at least once every three months to determine whether Criteria and Standards have been met over time and to develop a plan for improved adherence with Criteria and Standards in the future. Each pharmacy shall conduct a Periodic Self-audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's Criteria and Standards.
- (5) **Consumer Survey**
As a component of its Continuous Quality Improvement Program, each Pharmacy may conduct a Consumer Survey of patients who receive pharmaceutical products and services at the Pharmacy. A Consumer Survey should be conducted at least once per year. A statistically valid sampling technique may be used in lieu of surveying every patient. Each Pharmacy shall use the results of its Consumer Survey to evaluate its own performance at a particular time and over a period of time.
- (6) **Privilege from Discovery**
All information, communications, or data maintained as a component of a pharmacy Continuous Quality Improvement Program are privileged and confidential. All information, communications, or data furnished to any Professional Performance Evaluation committee, association board, organization board, or other entity and any

findings, conclusions, or recommendations resulting from the proceedings of such committee, board, or entity are privileged. The records and proceedings of any Professional Performance Evaluation committee, board, or entity are confidential and shall be used by such committee, board, or entity, and the members thereof, only in the exercise of the proper functions of the committee, board, or entity and shall not be public records nor be available for court subpoena or for discovery proceedings. The disclosure of confidential, privileged Professional Performance Evaluation committee information during advocacy, or as a report to the Board of Pharmacy, or to the affected Pharmacist or Pharmacy auxiliary personnel under review does not constitute either a waiver of confidentiality or privilege.

J. Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement.

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct Drug Therapy Management activities approved by the Practitioner. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents.

The Collaborative Pharmacy Practice Agreement shall include:

- (a) Identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
- (b) The types of Drug Therapy Management decisions that the Pharmacist is allowed to make, which may include:
 - (i) A detailed description of the types of diseases, Drugs, or Drug categories involved, and the type of Drug Therapy Management allowed in each case;
 - (ii) A detailed description of the methods, procedures, decision Criteria, and plan the Pharmacist is to follow when conducting Drug Therapy Management; and
 - (iii) A detailed description of the activities the Pharmacist is to follow in the course of conducting Drug Therapy Management, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;
- (c) A method for the Practitioner to monitor compliance with the Agreement and clinical outcomes where Drug Therapy Management by the Pharmacist has occurred and to intercede where necessary;
- (d) A description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes.
- (e) A provision that allows the Practitioner to override a Collaborative Practice decision

made by the Pharmacist whenever he or she deems it necessary or appropriate;

- (f) A provision that allows either party to cancel the Agreement by written notification;
- (g) An effective date; and
- (h) Signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.

Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(3) Initiation of the Collaborative Pharmacy Practice Agreement

The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate Drug Therapy Management for any particular patient.

(4) Documentation of Drug Therapy Management.

Documentation of Drug Therapy Management must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to receive it. Documentation of Drug Therapy Management shall be considered Protected Health Information.

(5) Review.

At a minimum, the written agreement shall be reviewed and renewed, and if necessary, revised every year.

K. Adverse Drug Reactions

Significant Adverse Drug Reactions shall be reported to the Practitioner and, in writing, to the Board of Pharmacy immediately upon discovery. Appropriate entry on the patient's record shall also be made.

L. Records of Dispensing/Delivery

- (1) Records of receipt, Dispensing, Delivery, Distribution, or other disposition of all Drugs or Devices are to be made and kept by Pharmacies for five years and shall include, but not be limited to:

- (a) quantity Dispensed for original and refills, if different from original;
- (b) date of receipt, Dispensing, Delivery, Distribution, or other disposition;
- (c) serial number (or equivalent if an institution);
- (d) the identification of the Pharmacist responsible for Dispensing;
- (e) name and Manufacturer of Drug Dispensed if Drug product selection occurs; and
- (f) records of refills to date.

- (2) Pharmacies that ship medications by mail, common carrier, or other type of Delivery service shall implement a mechanism to verify that a patient or caregiver has actually received the Delivered medication.

M. Computer Records

- (1) Systems Manuals

An up-to-date policy and procedure manual shall be developed by the Pharmacist-in-Charge that explains the operational aspects of the automated system and shall:

- (a) include examples of all required output documentation provided by the automated

system;

- (b) outline steps to be followed when the automated system is not operational due to scheduled or unscheduled system interruption;
- (c) outline regular and routine backup file procedure and file maintenance;
- (d) outline audit procedures, personnel code assignments, and personnel responsibilities; and
- (e) provide a quality assurance mechanism for data entry validation.

(2) Automated Data Processing System

- (a) Data storage and retrieval. The system shall have the capability of producing sight-readable information on all original and refill Prescription Drug Orders. The term "sight-readable" means that an authorized individual shall be able to examine the record and read the information from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy.
- (b) The system shall provide on-line retrieval (via CRT display or hard-copy printout) of original Prescription Drug Order information. Such information shall include, but not be limited to, the Prescription Drug Order requirements and records of Dispensing as indicated in Section II of this Rule. (*See Appendix B for Standardized Pharmacy Report.*)
- (c) The Pharmacist-in-Charge shall:
 - (i) Maintain a log book in which the Pharmacist responsible for Dispensing shall sign a statement each day attesting to the fact that the Prescription Drug Order information entered into the computer that day has been reviewed and is correct as shown. Such a log book shall be maintained at the Pharmacy employing such a system for a period of (number) years after the date of last Dispensing; or
 - (ii) Provide a printout of each day's Prescription Drug Order information. That printout shall be verified, dated, and signed in the same manner as signing a check or legal document (e.g., J.H. Smith or John H. Smith) by the individual Pharmacist verifying that the information indicated is correct. Such printout shall be maintained (number) years from the date of last Dispensing.
- (d) The computerized system shall have the capability of producing a printout of any Prescription Drug Order data. The system shall provide a refill-by-refill audit trail for any specified strength and dosage form of any Drug. Such an audit trail shall be by printout, and include the name of the prescribing Practitioner, name and location of the patient, quantity Dispensed on each refill, date of Dispensing of each refill, name or identification code of the Dispensing Pharmacist, and unique identifier of the Prescription Drug Order.
- (e) Any facility maintaining centralized prescription records shall be capable of sending a requested printout to the Pharmacy within 72 hours.

(3) Security

To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the Drug has been Dispensed, any alterations in Prescription Drug Order data shall be documented, including the identification of the Pharmacist responsible for the alteration.

(4) System Backup (Auxiliary Records Maintenance)

- (a) In the event of an unscheduled system interruption, sufficient patient data and Prescription Drug Order data should be available to permit reconstruction of such data within a two-hour time period for the Pharmacist to Dispense Drugs with sound professional judgment.
- (b) An auxiliary system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason and to ensure that all refills are authorized by the original Prescription Drug Order and that the maximum number of refills is not exceeded.
- (c) The auxiliary system shall be in place to provide for the maintenance of all necessary patient Drug information (as outlined in this rule) until the automated system becomes operational. However, nothing in this section shall preclude the Pharmacist from using professional judgment for the benefit of a patient's health and safety.
- (d) When the automated system is restored to operation, the information regarding Prescription Drug Orders Dispensed and refilled during the inoperative period shall be entered into the automated system within 96 hours.
- (e) Routine backup systems and procedures (hard copy, copy, disk, etc.) shall be in place and operational to ensure against loss of patient data.
- (f) In the event that permanent Dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy shall be notified within 24 hours.

N. Automated Pharmacy Systems

Automated Pharmacy Systems can be utilized in licensed pharmacies, remote locations under the jurisdiction of the Board of Pharmacy, and licensed health care facilities where legally permissible and shall comply with the following provisions.

- (1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained on-site in the Pharmacy for review by the Board of Pharmacy. Such documentation shall include, but is not limited to:
 - (a) name and address of the Pharmacy and/or licensed health care facility where the Automated Pharmacy System(s) is being used;
 - (b) Manufacturer's name and model;
 - (c) description of how the Device is used;
 - (d) quality assurance procedures to determine continued appropriate use of the automated Device; and
 - (e) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction.
- (2) Automated Pharmacy Systems should be used only in settings where there is an established program of Pharmaceutical Care that ensures medication orders are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacy practice.
- (3) All policies and procedures must be maintained in the Pharmacy responsible for the system and, if the system is not located within the facility where the Pharmacy is located, at the location where the system is being used.
- (4) Automated Pharmacy Systems shall have adequate security systems and procedures,

evidenced by written policies and procedures, to:

- (a) prevent unauthorized access;
 - (b) comply with federal and state regulations; and
 - (c) prevent the illegal use or disclosure of Protected Health Information.
- (5) Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements.
- (a) All events involving the contents of the Automated Pharmacy System must be recorded electronically.
 - (b) Records must be maintained by the Pharmacy and must be readily available to the Board. Such records shall include:
 - (i) identity of system accessed;
 - (ii) identification of the individual accessing the system;
 - (iii) type of transaction;
 - (iv) name, strength, dosage form, and quantity of the Drug accessed;
 - (v) name of the patient for whom the Drug was ordered; and
 - (vi) such additional information as the Pharmacist-in-Charge may deem necessary.
- (6) Access to and limits on access (e.g., security levels) to the Automated Pharmacy System must be defined by policy and procedures and must comply with state and federal regulations.
- (7) The Pharmacist-in-Charge shall have the sole responsibility to:
- (a) assign, discontinue, or change access to the system.
 - (b) ensure that access to the medications comply with State and Federal regulations.
 - (c) ensure that the Automated Pharmacy System is filled/stocked accurately and in accordance with established, written policies and procedures.
- (8) The filling/stocking of all medications in the Automated Pharmacy System shall be accomplished by qualified personnel under the supervision of a licensed Pharmacist.
- (9) A record of medications filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.
- (10) All containers of medications stored in the Automated Pharmacy System shall be packaged and labeled in accordance with Federal and State laws and regulations.
- (11) All aspects of handling controlled substances shall meet the requirements of all State and Federal laws and regulations.
- (12) The Automated Pharmacy System shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the Automated Pharmacy System, all in accordance with existing State and Federal law.
- (13) The Automated Pharmacy System shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing State and Federal law.

O. Centralized Prescription Processing

- (1) A Pharmacy may perform or outsource Centralized Prescription Processing services provided the parties:
 - (a) have the same owner; or
 - (b) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; and
 - (c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a Prescription Drug Order.
- (2) The parties performing or contracting for Centralized Prescription Processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Board for review upon request and that includes, but is not limited to, the following:
 - (a) A description of how the parties will comply with federal and state laws and regulations;
 - (b) The maintenance of appropriate records to identify the responsible Pharmacist(s) in the Dispensing and counseling processes;
 - (c) The maintenance of a mechanism for tracking the Prescription Drug Order during each step in the Dispensing process;
 - (d) The maintenance of a mechanism to identify on the prescription label all Pharmacies involved in Dispensing the Prescription Drug Order;
 - (e) The provision of adequate security to protect the integrity and prevent the illegal use or disclosure of Protected Health Information;
 - (f) The maintenance of a Continuous Quality Improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

P. Disposal of Controlled Substances

Any Persons legally authorized to possess controlled substances in the course of their professional practice or the conduct of their business shall dispose of such Drugs by the following procedures:

- (1) The responsible individual shall send the Board of Pharmacy a list of the controlled substances to be disposed of, including the name(s) and quantity of the Drug(s).
- (2) The Board shall authorize and instruct the applicant to dispose of the controlled substances in one of the following manners:
 - (a) By Delivery to an agent of the Board of Pharmacy or the Board of Pharmacy office;
 - (b) By destruction of the Drugs in the presence of a Board of Pharmacy officer, agent, inspector, or other authorized individual; or
 - (c) By such other means as the Board of Pharmacy may determine to assure that the Drugs do not become available to unauthorized Persons.

Q. Patient Compliance and Intervention Programs

Patient Compliance and Intervention Programs designed to promote improved medication

use behaviors, such as compliance, appropriate monitoring and self-reporting, increased patient knowledge, and improved therapy options, shall comply with established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Patient Compliance and Patient Intervention Programs. *(See Appendix F for Model Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Patient Compliance and Patient Intervention Programs)*

KANSAS

68-7-20. Shared services. (a) (1) "Order" means either of the following:

(A) A prescription order as defined in K.S.A. 65-1626 and amendments thereto; or

(B) a medication order as defined in K.A.R. 68-5-1.

(2) "Shared order filling" means the following:

(A) Preparing, packaging, compounding, or labeling an order, or any combination of these functions, by a person authorized by the pharmacy act to do so and located at a pharmacy on behalf of and at the request of another pharmacy; and

(B) returning the filled order to the requesting pharmacy for delivery to the patient or patient's agent or, at the request of the requesting pharmacy, directly delivering the filled order to the patient.

(3) "Shared order processing" means the following order processing functions that are performed by a person authorized by the pharmacy act and located at a pharmacy, on behalf of and at the request of another pharmacy:

(A) Interpreting and entering the order; and

(B) performing drug utilization reviews, claims adjudication, refill authorizations, or therapeutic interventions, or any combination of these functions.

(4) "Shared services" means shared order filling or shared order processing, or both.

- (3) report to the board as soon as practical the results of any disciplinary action taken by another state's pharmacy board involving shared services;
- (4) maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy;
- (5) maintain a mechanism to identify on the prescription label all pharmacies involved in filling the order;
- (6) provide for adequate security to protect the confidentiality and integrity of patient information; and
- (7) be able to obtain for inspection any required record or information within 72 hours of any request by a board representative.

(e) Each pharmacy providing or utilizing shared services shall adopt and maintain a joint policies and procedures manual that meets both of the following criteria:

(1) The manual describes how compliance with the pharmacy act and the board's regulations will be accomplished while engaging in shared services.

(2) A copy of the manual is maintained in each pharmacy.

(f) Nothing in this regulation shall prohibit an individual pharmacist licensed in Kansas who is an employee of or under contract with the pharmacy or a pharmacy technician, pharmacy student, or intern working under the direct supervision and control of the pharmacist from accessing the pharmacy's electronic database from inside or outside the pharmacy and performing the order processing functions permitted by the pharmacy act, if both of the following conditions are met:

(1) The pharmacy establishes controls to protect the privacy and security of confidential records.

(2) None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database. (Authorized by K.S.A. 65-1630 and 65-1656; implementing K.S.A. 65-1626(cc), 65-1626a, 65-1637, 65-1642, and 65-1656; effective P-_____.)

MISSOURI

C. Any decision made concerning the approval of a temporary or mobile pharmacy shall not interfere with any rights or privileges of a pharmacy permit holder at the original location of operation or prevent a permit holder from applying for a change of location as outlined in 4 CSR 220-2.020(4).

AUTHORITY: sections 338.210 and 338.280, RSMo 1994.* Original rule filed May 4, 1995, effective Dec. 30, 1995.

*Original authority: 338.210, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.

4 CSR 220-2.018 Prescription Requirements

PURPOSE: This rule establishes requirements for information required on prescriptions.

(1) In order for a prescription to be valid for purposes of dispensing a medication by a pharmacy, it must conform to all requirements as outlined in sections 338.056 or 338.196, RSMo, and contain the following information:

(A) The prescription date and a unique, readily retrievable identifier;

(B) The name of the patient(s);

(C) The prescriber's name, if an oral prescription, signature if a written prescription;

(D) Any prescriber indication of name and dosage of drug, directions for use, name and dosage of drug dispensed;

(E) The number of refills, when applicable;

(F) The quantity dispensed in weight, volume or number of units;

(G) The initials or name of the pharmacist responsible for processes in dispensing or compounding of the prescription;

(H) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills or authority to substitute a drug;

(I) The address of the prescriber and the patient when the prescription is for a controlled substance;

(J) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(K) Any prescription, when it is for a controlled substance, must comply with all requirements of federal and state controlled substance laws.

(2) The information specified in section (1) shall be required and recorded on all hand-

written, telephone, oral and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy.

AUTHORITY: sections 338.095, 338.100, 338.140, 338.240 and 338.280, RSMo 2000.* Original rule filed May 4, 1995, effective Dec. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001.

*Original authority: 338.095, RSMo 1939; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999; 338.140, RSMo 1939; amended 1981, 1989, 1997; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.

4 CSR 220-2.020 Pharmacy Permits

PURPOSE: This rule outlines the requirements for obtaining and maintaining a pharmacy permit.

(1) The fiscal year of the board shall be as provided by law. All permits for the operation of a pharmacy shall expire on the date specified by the director of the Division of Professional Registration by appropriate rule.

(2) A pharmacy permit may be issued on the application of the owners. If the owner is a corporation or partnership, an officer of the corporation or a partner must sign the application as the applicant. In the case where a pharmacy is owned and operated by a person(s) who is a licensed pharmacist and in active charge of the pharmacy, the application for permit can be made by either party.

(A) An application for a pharmacy permit will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(3) When a pharmacy changes ownership, the original permit becomes void on the effective date of the change of ownership. Before any new business entity resulting from the change opens a pharmacy for business, it must obtain a new permit from the board. However, a grace period of thirty (30) days will be allowed after the change of ownership.

(A) A change of ownership of a pharmacy owned by a sole proprietor is deemed to have occurred when—

1. The business is sold and the sale becomes final;

2. The proprietor enters into a partnership with another individual or business entity; or

3. The proprietor dies; provided, however, that the proprietor's estate may contin-

ue to operate the pharmacy under the licensed pharmacist in good standing in this state, but in no case for a period of more than one (1) year and only so long as appropriate pharmacy permit fees are paid.

(B) A corporation is considered by law to be a separate person. If a corporation owns a pharmacy, it is not necessary to obtain a new license if the owners of the stock change. However, as a separate person, if the corporation begins ownership of a pharmacy or ceases ownership of that pharmacy, a new license must be obtained regardless of the relationship of the previous or subsequent owner to the corporation. It is not necessary to obtain a new license when ownership of the stock in the corporation changes. It is necessary to file written notice with the State Board of Pharmacy within ten (10) days after that change occurs. This notification must be in writing and certified.

(C) All individuals or business entities owning twenty-five percent (25%) or more of the ownership of any entity owning a pharmacy must notify the board within thirty (30) days of acquiring the percentage.

(4) If an individual or business entity operating a pharmacy changes the location of the pharmacy to a new facility (structure), the pharmacy shall not open for business at the new location until the board or its duly authorized agent has inspected the premises of the new location and approved it and the pharmacy as being in compliance with section 338.240, RSMo and all other provisions of the law. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a pharmacy at the new location and the permit shall bear the same number as the previous pharmacy permit. However, the permit remains valid if the pharmacy address changes, but not the location and an amended permit will be issued without charge under these circumstances.

(A) Remodeling of a licensed pharmacy within an existing structure shall be deemed to have occurred when any change in the storage conditions of the Schedule II controlled substances is made or new connections to water/sewer resources are made or any changes in the overall physical security of drugs stored in the pharmacy as defined in 4 CSR 220-2.010(1)(H) are made. Remodeling as defined within this section will not require the initiation of any change of location procedures. Satisfactory evidence of plans for any remodeling of a pharmacy must be provided to the board office thirty (30) days in advance of commencing such changes along with an



affidavit showing any changes to the pharmacy physical plant and the projected completion date for any remodeling.

(5) Permits, when issued, will bear an original number. Permits must be posted in a conspicuous place in the pharmacy to which it is issued.

(6) No pharmacy permit will be issued unless the pharmacy area is under the direct supervision of a licensed pharmacist in good standing with the Missouri State Board of Pharmacy, who meets the requirements of 4 CSR 220-2.090.

(7) If the owner/applicant is not the licensed pharmacist-in-charge, then the pharmacist-in-charge must meet the requirements of 4 CSR 220-2.090 and complete the pharmacist-in-charge affidavit of the permit application and have it notarized.

(8) The names of all pharmacists regularly working in a pharmacy shall be clearly displayed on the premises of every establishment having a pharmacy permit.

(9) The following classes of pharmacy permits or licenses are hereby established:

(A) Class A: Community/Ambulatory. A pharmacy that provides services as defined in section 338.010, RSMo to the general public;

(B) Class B: Hospital Outpatient Pharmacy. A pharmacy operated by and located within a hospital that provides services as defined in section 338.010, RSMo to patients other than to the hospital's inpatient population;

(C) Class C: Long-Term Care. A pharmacy that provides services as defined in section 338.010, RSMo by the dispensing of drugs and devices to patients residing within long-term care facilities. A long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients;

(D) Class D: Home Health. A pharmacy that provides services as defined in section 338.010, RSMo for patients in a public or private residence who are under the supervision of a home health or hospice agency;

(E) Class E: Radiopharmaceutical. A pharmacy that is not open to the general public and provides services as defined in section 338.010, RSMo limited to the preparation and dispensing of radioactive drugs as defined by the Food and Drug Administration (FDA) to health care providers for use in the treatment or diagnosis of disease and that maintains a qualified nuclear pharmacist as the pharmacist-in-charge;

(F) Class F: Renal Dialysis. A pharmacy that is not open to the general public that provides services as defined in section 338.010, RSMo limited to the dispensing of renal dialysis solutions and other drugs and devices associated with dialysis care;

(G) Class G: Medical Gas. A pharmacy that provides services as defined in section 338.010, RSMo through the provision of oxygen and other prescription gases for therapeutic uses;

(H) Class H: Sterile Product Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a sterile pharmaceutical as defined in 4 CSR 220-2.200(1) and (15). Pharmacies providing sterile pharmaceuticals within the exemptions outlined in 4 CSR 220-2.200 shall not be considered a Class H pharmacy; and

(I) Class I: Consultant. A location where any activity defined in section 338.010, RSMo is conducted, but which does not include the procurement, storage, possession or ownership of any drugs from the location.

(J) Class J: Shared Service. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions.

(10) Pharmacy applications for initial licensure or renewals of a license shall accurately note each class of pharmacy that is practiced at the location noted on the application or renewal thereof. The permit (license) issued by the board shall list each class of licensure that the pharmacy is approved to engage in. Whenever a change in service classification occurs at a pharmacy the permit must be sent to the board with a notarized statement explaining any additions or deletions of pharmacy classes that are to be made.

AUTHORITY: sections 338.140, RSMo 2000 and 338.220, RSMo Supp. 2001 and Omnibus State Reorganization Act of 1974 (Appendix B). * Original rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Oct. 27, 1970, effective Nov. 6, 1970. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Emergency amendment filed July 15, 1981, effective Sept. 28, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 10, 1981, effective Nov. 12, 1981. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed March 14, 1983, effective June 11, 1983. Amended: Filed Feb. 11, 1985,

effective May 11, 1985. Amended: Filed Dec. 16, 1985, effective May 11, 1986. Amended: Filed Aug. 1, 1986, effective Nov. 13, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Jan. 6, 1998, effective Aug. 30, 1998. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003.

*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001.

Op. Atty. Gen. No. 316, Tracy (9-16-64). Restrictions imposed by city zoning ordinance provide no basis for board to refuse to license a pharmacy where pharmacy is otherwise qualified for a license and where these restrictions in no way affect the actual filling of prescriptions.

Op. Atty. Gen. No. 1, Allen (12-8-61). Rule promulgated by board requiring the presence of registered pharmacist at all times that a drug store is open for business is invalid as unreasonable enlargement of statutory requirement that presence of pharmacist is necessary only when prescriptions are compounded or sold.

Op. Atty. Gen. No. 70, Missouri State Board of Pharmacy (10-6-52). Proprietor of wholesale drug business must be licensed pharmacist or have at least one in his/her employ.

4 CSR 220-2.025 Nonresident Pharmacies

PURPOSE: This rule establishes licensure guidelines for nonresident pharmacies.

(1) Nonresident pharmacies shall not ship, mail or deliver prescription drugs into Missouri without first obtaining a pharmacy license from the Missouri Board of Pharmacy. An exemption to licensure is allowed when a nonresident pharmacy provides a prescription drug in an emergency situation or supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located or provides medications upon receipt of a prescription or physician order for patients in institutional settings and the nonresident pharmacy is not recognized as a primary provider.

(2) To obtain a license as a pharmacy, a nonresident pharmacy must comply with each of the following:

Missouri Revised Statutes

Chapter 338

Pharmacists and Pharmacies

Section 338.010

August 28, 2003

Practice of pharmacy defined--auxiliary personnel--nonprescription drugs.

338.010. 1. The "practice of pharmacy" shall mean the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his duties. This assistance in no way is intended to relieve the pharmacist from his responsibilities for compliance with this chapter and he will be responsible for the actions of the auxiliary personnel acting in his assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, podiatry, or veterinary medicine, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220, RSMo, in the compounding or dispensing of his own prescriptions.

2. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

3. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

(RSMo 1939 § 10005, A.L. 1951 p. 737, A.L. 1989 S.B. 39, A.L. 1990 H.B. 1287)

Prior revisions: 1929 § 13140; 1919 § 4712; 1909 § 5764

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Missouri General Assembly

**NEW
JERSEY**

NEW JERSEY REGISTER
VOLUME 36, NUMBER 1
MONDAY, JANUARY 5, 2004
RULE PROPOSAL
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
DUTIES OF REGISTERED PHARMACIST-IN-CHARGE; PROCEDURES FOR CENTRALIZED
PRESCRIPTION HANDLING; LABELING REQUIREMENTS

Proposed Amendments: N.J.A.C. 13:39-3.18 and 5.9

Proposed New Rule: N.J.A.C. 13:39-5.10

Authorized By: Board of Pharmacy, Joanne Boyer, Executive Director.

Authority: N.J.S.A. 45:14-32, 45:14-33, 45:14-36 and 45:14-36.1.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2004-1.

Submit comments by March 5, 2004 to:

Joanne Boyer, Executive Director

Board of Pharmacy

PO Box 45013

The agency proposal follows:

Summary

The New Jersey Board of Pharmacy (the Board), pursuant to its authority at N.J.S.A. 45:14-36, proposes new rule N.J.A.C. 13:39-5.10 to establish procedures for regulating the handling of prescriptions by centralized pharmacies, commonly known or referred to as "central fill" pharmacies and/or "central processing" pharmacies. The Board also proposes to amend N.J.A.C. 13:39-3.18 which delineates the duties of the registered pharmacist-in-charge and N.J.A.C. 13:39-5.9 which regulates the labeling of medication containers.

With this proposal, the Board authorizes the designation and use of pharmacies as "central fill" pharmacies. A central fill pharmacy provides the packaging, labeling and delivery of a prescription to another pharmacy for the purpose of filling or refilling that prescription on behalf of that other pharmacy which then dispenses the prescription to the patient. To understand this concept, the Board has, at subsection (a) of proposed new rule N.J.A.C. 13:39-5.10, identified four basic components involved in the handling of a prescription which are: intake, processing, fulfillment and dispensing. The handling of a prescription through a central model requires two or more pharmacies to share responsibility for performing the component functions of intake, processing, fulfillment and dispensing the prescription (subsection (b) of the new rule). The Board, at subsection (c) of the new rule, has identified the functional components of pharmacies which may agree to engage in the handling of prescriptions through a centralized model. These pharmacies are identified in the new rule as: an intake or originating pharmacy; a central processing pharmacy; a central fill pharmacy; and a dispensing pharmacy. In subsection (d) of the new rule, the Board sets out the requirements that the component pharmacies which wish to provide prescriptions through a centralized model must adhere to. Any or all of the pharmacies participating in central prescription handling must have a contractual agreement to provide such services or must have the same owner. Subsection (d) also provides that prior to engaging in central prescription handling, all pharmacies that are parties to central prescription handling must make a single application to the Board for prior authorization. In this application, the pharmacies must delineate the scope of practice of each pharmacy, as well as the specific Board rules with which each pharmacy will comply.

Subsection (d) also provides that all pharmacies that are engaged in central prescription handling must maintain an audit trail that records and documents the names of individuals and the component functions they perform for each step of the process. The audit trail must be maintained for five years from the date a prescription is filled or refilled. The oldest four years of information must be maintained in a manner that is

retrievable and readable within two weeks, and the most recent one year of information must be immediately retrievable and readable.

Subsection (d) also provides that a prescription that is prepared and dispensed through a central model must contain a label with specific information as outlined in the rule. In addition, the patient to whom the prescription is dispensed must be provided information which directs the patient to the pharmacy to be contacted if the patient has any questions about the prescription. This information must be readily apparent and must include the pharmacy phone number and when the contact pharmacist is available. The telephone service must be provided at no cost to the patient. All pharmacies that engage in central prescription handling must maintain a common policies and procedures manual which identifies which pharmacy will be responsible for each of the component functions of handling the prescriptions and which pharmacy will be responsible for ensuring compliance with specific Board rules. The manual must also include how to maintain the required audit trail. The policies and procedures manual must be made available to the Board upon request. All of the pharmacies that engage in central prescription handling must share a common electronic file and are held responsible for ensuring that each prescription has been properly filled.

Subsection (e) provides direction for pharmacies engaging in central prescription handling of controlled substances. Prescriptions for controlled substances may be filled or refilled through a centralized process consistent with the Federal requirements outlined in 21 C.F.R. § 1300 et seq. Recent amendments to Drug Enforcement Administration (DEA) regulations now permit the utilization of central fill pharmacies for the dispensing of controlled substances, subject to certain restrictions. These amendments will impose various requirements upon pharmacies which wish to process prescriptions for controlled substances in a centralized manner.

The Board notes that subsection (c) provides for the transmission of a prescription by a prescribing practitioner directly to a centralized pharmacy by facsimile and/or electronic means, consistent with the requirements set forth in N.J.A.C. 13:39-5.8A and 5.8B, which were proposed as new rules by the Board in the New Jersey Register at 34 N.J.R. 3064(a) on September 3, 2002. New rules N.J.A.C. 13:39-5.8A and 5.8B establish standards for pharmacies receiving, filling and dispensing prescriptions transmitted by practitioners by facsimile and/or electronic communication. The new rules became effective on September 15, 2003. See 35 N.J.R. 4290(a).

During its consideration of this new central prescription handling initiative, the Board reviewed the current requirements of the labeling rule at N.J.A.C. 13:39-5.9 and decided to amend the rule in order to make the labeling requirements for all pharmacies throughout the State more consistent with the labeling requirements that will be imposed upon pharmacies engaging in central prescription handling. To accomplish this, the Board is deleting the requirement that the label contain the name of the registered pharmacist-in-charge. The

Board believes that requiring the name of the registered pharmacist-in-charge, who may or may not be the dispensing pharmacist, to appear on the label may confuse patients who have questions about their prescriptions and would like to contact the pharmacist who dispensed the medication. In light of this change, the Board is deleting paragraph (c)8 of N.J.A.C. 13:39-3.18, which imposes a duty upon the registered pharmacist-in-charge to ensure that all prescription labels contain his or her name. The subsequent paragraph of N.J.A.C. 13:39-3.18 will be recodified without change.

The Board is also amending the labeling rule to now require that the label state the strength of the medication and the quantity dispensed. In addition, the labeling rule is amended by substituting the words "use by date" and "expiration date" to clarify for the patient the latest time when the medication should be used. In new subsection (b) in N.J.A.C. 13:39-5.9, the Board will require that the patient's name, the name of the medication and the directions for use be in either larger type, in a different color or in bold in order to highlight this information from the rest of the information contained on the label.

The Board notes that the proposed amendments to the labeling requirements at N.J.A.C. 13:39-5.9, if adopted, would not be effective immediately. The Board recognizes that any changes to existing prescription labels would likely require pharmacies to change their current computer software and programs. The Board believes that it is necessary to provide pharmacists and pharmacies with sufficient time within which to complete such changes and, therefore, the Board intends to provide, on adoption, that all prescription labels must conform to the proposed amendments within six months, or 180 days, of the effective date of the changes.

The Board has provided a 60-day comment period for this notice of proposal. Therefore, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed new rule which would establish procedures and permit the handling of prescriptions at a centralized pharmacy is expected to have a beneficial impact on pharmacists, pharmacies and consumers who frequent pharmacies to drop off and pick up prescriptions. Given the aging population and longer life expectancies, and the introduction of new medicines which promote a longer and healthier life, the number of prescriptions issued each year has been increasing steadily and will continue to increase for years to come. At the same time, there is a recognized need for additional pharmacists to handle the increase in prescriptions issued, but the number of individuals entering the pharmacy profession has been steadily declining. Hence, a pharmacist shortage exists and is expected to continue. The Board anticipates that a centralized prescription handling model, as contemplated by the proposed new rule, would shift the prescription filling function to a central pharmacy, thereby freeing up the pharmacies at the point where the

prescription is dispensed to the patient/consumer. This benefits the pharmacist who has more time to counsel patients at the point of dispensing and benefits the patient/consumer through more direct contact with the dispensing pharmacist. The Board also anticipates that the time spent by consumers waiting for prescriptions may decrease while at the same time improving the pharmacist's work environment and job satisfaction. Pharmacies that enter into centralized prescription handling may achieve operational efficiencies, improve quality control and reduce prescription errors.

The proposed amendments to the labeling rule at N.J.A.C. 13:39-5.9 are also expected to have a positive impact on both pharmacists and consumers. Deleting the name of the registered pharmacist-in-charge from the label should eliminate consumer confusion because the name of the pharmacist on the label may not be the name of the person who actually filled the prescription. By labeling the strength of the medication and the quantity dispensed, the patient/consumer will know the potency of the medication being taken and how much medication has been dispensed. The proposed amendment changing "expiration date" to "use by date" will direct the patient/consumer to the date by when the medication may be taken. Lastly, the amendments requiring that the name of the patient, the name of the medication and the directions be in a larger type, a different color or in bold will assist the patient/consumer in identifying the medication and its proper use.

Economic Impact

The proposed new rule does not impose any economic costs on pharmacies or pharmacists. Pharmacies which decide to handle prescriptions in a centralized manner may experience a reduction in inventory costs through the reduction and/or elimination of slow moving and/or expensive inventory. It may be possible that such economies of scale in centralized functions may reduce the cost of handling each prescription.

The proposed amendments to the labeling rule at N.J.A.C. 13:39-5.9 may impose some administrative costs on pharmacies by causing the pharmacies to reprogram computer equipment with the new information required to be on the label. Such one-time expense, if any, is not estimated, but the Board believes the benefits the new labeling requirements will achieve outweigh the conversion costs.

Federal Standards Statement

A Federal standards analysis is not required because the proposed new rule and amendments are governed by N.J.S.A 45:14-1 et seq., and, therefore, are not subject to any Federal requirements or standards. The Board notes, however, that pharmacies wishing to handle controlled substance prescriptions in a centralized manner must do so consistent with the Federal DEA standards articulated at 21 C.F.R. § 1300 et seq.

Jobs Impact

The Board does not anticipate that the proposed new rule and amendments will result in the creation or loss of jobs in the State.

Agriculture Industry Impact

The proposed new rule and amendments will have no impact on the agriculture industry in the State.

Regulatory Flexibility Statement

The Regulatory Flexibility Act (the Act), N.J.S.A. 52:14B-16 et seq., requires the Board to provide a description of the types and an estimate of the number of small businesses to which the proposed new rule and amendments will apply. Currently, the Board licenses approximately 12,291 pharmacists. If Board licensees are considered "small businesses," within the meaning of the Act, then the following analysis applies.

The Act requires the Board to set forth the reporting, recordkeeping and other compliance requirements of the proposed new rule and amendments, including the kinds of professional services likely to be needed to comply with requirements. The Act further requires the Board to estimate the initial and annual compliance costs of the proposed new rule and amendments, to outline the manner in which it has designed the new rule and amendments to minimize any adverse economic impact upon small businesses, and to set forth whether the new rule and amendments establish differing compliance requirements for small businesses.

The proposed new rule will not impose any reporting requirements upon Board licensees. A recordkeeping requirement is proposed at N.J.A.C. 13:39-5.10(d) 3, where all pharmacies involved in central prescription handling must maintain, for five years, an audit trail of the individuals involved and the function performed by each during the prescription handling process.

The proposed new rule also imposes compliance requirements which are found in subsection (d) and (e) and are discussed above in the Summary. The proposed amendments to the labeling rule also impose new compliance requirements which are discussed above in the Summary.

It is not anticipated that any additional professional services will be needed to comply with the proposed new rule and amendments. In order to ensure that all pharmacies which intend to engage in central prescription handling adhere to the same standards, no differing compliance requirements are provided based upon the size of the pharmacy.

Smart Growth Impact

The Board does not believe that the proposed new rule and amendments will have any impact upon the achievement of smart growth or upon the implementation of the State Development and Redevelopment Plan.

Full text of the proposal follows :

<< NJ ADC 13:39-3.18 >>

13:39-3.18 Registered pharmacist-in-charge

(a)-(d) (No change.)

(e) A registered pharmacist-in-charge shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to ensure the fulfilling of the following responsibilities:

1.-7. (No change.)

<<-8. Ensuring the use of prescription labels naming the registered pharmacist-in-charge;->>

Recodify existing 9.-14. as 8.-13. (No change in text.)

<< NJ ADC 13:39-5.9 >>

13:39-5.9 Labeling

(a) The dispensed container for any product shall bear a permanently affixed label with at least the following information:

<<-1. The name of the registered pharmacist-in-charge;->>

Recodify existing 2.-3. as 1.-2. (No change in text.)

<<-4.->><<+3.+>> The brand name of generic name<<-;->> <<+ and+>>

<<-i. If->> <<+if+>> generic, the name of the manufacturer;

<<+4. The strength of medication, where applicable;+>>

<<+5. The quantity dispensed;+>>

<<-5.->><<+6.+>> (No change in text.)

<<-6.->><<+7.+>> A CDS cautionary label<<+, where applicable+>>;

<<-7.->><<+8.+>> (No change in text.)

<<-8.->><<+9. +>>Initials of the dispensing pharmacist;

<<-9.->><<+10.+>> The <<-prescriber's->><<+ prescriber+>> name;

<<-10.->><<+11.+>> (No change in text.)

<<-11.->><<+12.+>> Directions for use; and

<<-12.->><<+13.+>> The <<-expiration date->> <<+phrase "use by" followed by the product's use by date,+>> if dispensed in any packaging other than the manufacturer's original packaging.

i. For purposes of this paragraph, "<<-expiration->> <<+use by+>> date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container.

<<+(b) The patient name, the brand or generic name of the medication, and the directions for use shall appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (a) above.+>>

<<-(b)->><<+(c)+>> In addition to the requirements set forth in (a) <<+and (b)+>> above, the dispense<<+d+>> container for any product shall bear all auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist.

<< NJ ADC 13:39-5.10 >>

<<+13:39-5.10 Procedures for centralized prescription handling+>>

- <<+(a) The four component functions of handling a prescription are intake, processing, fulfillment and dispensing.+>>
- <<+(b) Central prescription handling entails two or more licensed pharmacies sharing responsibility for performing the four component functions of handling a prescription.+>>
- <<+(c) The following pharmacies may engage in central prescription handling: an intake or originating pharmacy; a central processing pharmacy; a central fill pharmacy; and a dispensing pharmacy. The four component functions of handling a prescription shall be performed by the following pharmacies:+>>
- <<+1. An intake or originating pharmacy, which is a licensed pharmacy that received the patient's or prescribing practitioner's request to fill or refill a prescription. A central processing pharmacy or a central fill pharmacy, as delineated in (c)2 and 3 below, may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy as provided in N.J.A.C. 13:39-5.8A and 5.8B or if the patient requested the refill from that pharmacy;+>>
- <<+2. A central processing pharmacy, which is a licensed pharmacy that engages in prescription review by performing functions that may include, but are not limited to, data entry, prospective drug review, refill authorizations, interventions, patient counseling, claims submission, claims resolution and adjudication;+>>
- <<+3. A central fill pharmacy, which is a licensed pharmacy engaging in central prescription handling by filling and/or refilling prescriptions which includes the preparation and packaging of the medication; and+>>
- <<+4. A dispensing pharmacy, which is a licensed pharmacy that receives the processed prescription and/or the filled or refilled prescription for dispensing to the patient or to the patient's authorized representative.+>>
- <<+(d) Two or more of the licensed pharmacies delineated in (c) above may engage in central prescription handling provided:+>>
- <<+1. Any or all of the pharmacies participating in central prescription handling have a contractual agreement to provide such services or have the same owner;+>>
- <<+2. Prior to engaging in central prescription handling, all pharmacies that are parties to the central prescription handling obtain Board approval. The pharmacies shall make a single application to the Board, delineating the scope of practice of each pharmacy and the specific rules in this chapter with which each pharmacy shall comply;+>>

- <<+3. An audit trail is maintained that records and documents the name(s) of the individual(s) and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling. The audit trail shall be maintained for not less than five years from the date the prescription is filled or refilled. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be immediately retrievable and readable;+>>>
- <<+4. The dispensed prescription for any product bears a permanently affixed label with at least the following information:+>>>
- <<+i. The brand name or generic name, and if generic, the name of the manufacturer;+>>>
- <<+ii. The strength of medication, where applicable;+>>>
- <<+iii. The quantity dispensed;+>>>
- <<+iv. The date upon which prescription medication is dispensed;+>>>
- <<+v. A CDS cautionary label, where applicable and when permitted by law;+>>>
- <<+vi. The patient name;+>>>
- <<+vii. The prescriber name;+>>>
- <<+viii. The prescription number;+>>>
- <<+ix. Directions for use;+>>>
- <<+x. The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging. For purposes of this paragraph, "use by date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container;+>>>
- <<+xi. All auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist; and+>>>
- <<+xii. The name, address and telephone number of any or all of the following;+>>>

<<+(1) The intake pharmacy;+>>

<<+(2) The central processing pharmacy;+>>

<<+(3) The central fill pharmacy; and/or+>>

<<+(4) The dispensing pharmacy;+>>

<<+5. The patient name, the brand or generic name of the medication, and the directions for use appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (d)4 above;+>>

<<+6. The patient is provided with written information, either on the prescription label or with the prescription container, that indicates which pharmacy to contact if the patient has any questions about the prescription or the medication. The written information provided to the patient shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service shall be available at no cost to the pharmacy's primary patient population;+>>

<<+7. All pharmacies that are to engage in central prescription handling maintain a common policies and procedures manual which designates who shall be responsible for each of the component functions of handling the prescription and for ensuring compliance with the Board rules set forth in this chapter. The policies and procedures manual shall also include maintenance of the audit trail required by (d)3 above. The policies and procedures manual shall be made available to the Board upon request;+>>

<<+8. All pharmacies that are to engage in central prescription handling share a common electronic file; and+>>

<<+9. All pharmacies that are to engage in central prescription handling are responsible for ensuring that the prescription has been properly filled.+>>

<<+(e) A prescription for a controlled substance may be filled or refilled by pharmacies engaging in central prescription handling when permitted by law, consistent with Federal requirements set forth at 21 C.F.R. § 1300 et seq.+>>



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**NORTH
CAROLINA**

- (3) The restocking of automated dispensing devices.
- (c) Only persons authorized by the pharmacist-manager may remove drugs from the dispensing devices and only in the quantity of doses needed to satisfy immediate patient needs. Should a violation of the foregoing occur, the pharmacist-manager shall conduct an investigation and report any violations to the entity having jurisdiction over these issues.
- (d) Bar code scanning of drug packaging and storage units may be utilized as a quality control mechanism if this technology is available in the automated dispensing system.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. April 1, 1999;
Amended Eff. August 1, 2002

.1815 EMERGENCY PRESCRIPTION REFILL DUE TO INTERRUPTION OF MEDICAL SERVICES

In the event a pharmacist or device and medical equipment permit holder receives a request for a prescription refill and the pharmacist or permit holder is unable to obtain readily refill authorization from the prescriber because of the prescriber's inability to provide medical services to the patient, the pharmacist or permit holder may dispense a one-time emergency supply of up to 90 days of the prescribed medication, provided that:

- (1) The prescription is not for a Schedule II controlled substance;
- (2) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;
- (3) In the pharmacist's or permit holder's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences;
- (4) The dispensing pharmacist or permit holder creates a written order entered in the pharmacy's automated data processing system containing all of the prescription information required by Section .2300 of these Rules and signs that order;
- (5) The dispensing pharmacist or permit holder notifies, or makes a good faith attempt to notify, the prescriber or the prescriber's office of the emergency dispensing within 72 hours after such dispensing.

History Note: Authority G.S. 90-85.6; 90-85.25; 90-85.32
Temporary Adoption Eff. October 29, 1998
Eff. August 1, 2000.

.1816 PROCEDURES FOR CENTRALIZED PROCESSING OF PRESCRIPTION ORDERS

- (a) A pharmacy permitted by the Board may process a request for the filling or refilling of a prescription order received by a pharmacy within this State, provided:
- (1) The pharmacy that is to fill or refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.
 - (2) The prescription container:
 - (A) is clearly labeled with all information required by Federal and State laws and regulations; and
 - (B) clearly shows the name and address of the pharmacy refilling the prescription and the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient,
 - (3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
 - (4) Both pharmacies maintain complete and accurate records of the prescription, including:
 - (A) the name of the pharmacist who fill or refills the prescriptions
 - (B) the name of the pharmacy filling or refilling the prescription; and
 - (C) the name of the Pharmacy that received the fill or refill request.
 - (5) The pharmacy that fills or refills the prescription and the pharmacy that receives the prescription for dispensing to the patient share a common electronic file,

- (6) The originating pharmacy is responsible for compliance with the requirements of Federal and State laws and regulations regarding recordkeeping and patient counseling.
- (b) Nothing in this Rule shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.
- Authority G.S. 90-85.6; 90-85-32;*
Eff. August 1, 2000.

21 NCAC 46 .1817 PROOF OF IDENTIFICATION

(a) As a precondition to filling any prescription or dispensing any drug, a pharmacist or person acting at the direction of a pharmacist may demand, inspect and record proof of identification, including valid photographic identification, from any patient presenting a prescription or any person acting on behalf of the patient. Valid photographic identification includes but is not limited to the following:

- (1) A valid motor vehicle operator's license;
- (2) A valid identification card;
- (3) A valid United States passport; or
- (4) Other valid, tamper-resistant, photographic identification.

(b) A pharmacist or person acting at the direction of a pharmacist may exercise discretion and refuse to fill any prescription or dispense any drug if unsatisfied as to the legitimacy or appropriateness of any prescription presented, the validity of any photographic identification or the identity of any patient presenting a prescription or any person acting on behalf of the patient. Refusal to fill pursuant to this Paragraph shall be noted on the prescription by the pharmacist or person acting at the direction of a pharmacist.

History Notes: Authority G.S. 90-85.6; 90-85.32;
Eff. August 1, 2002

21 NCAC 46 .1818 PRESCRIPTION LABELS

Prescription labels shall list at a minimum the generic name of the drug, even if the generic drug is unavailable to dispense or even if the substitution of a generic drug is not authorized.

History Note: Authority G.S. 90-85.6; 90-85.32;
Eff. January 1, 2006.

SECTION .1900 – FORMS

.1901 DEFINITION

For use in the discharge of the statutory duties of the Board, it has adopted certain official forms which are described in this Section. Forms referred to in this Chapter are those forms described in this Section, and are available from the Board's office.

History Note: Authority G.S. 90-85.6;
Eff. April 1, 1983; Amended Eff. May 1, 1989.

.1902 APPLICATION FOR PHARMACIST'S LICENSE

The form for application for a pharmacist's license is "Application for Examination and Registered Pharmacist Certificate." All applicants for admission to the examination for licensure as a pharmacist shall submit this form. In addition to the normal questions of identification, this form requests responses on education, experience, prior activity, proof of qualifications and character.

History Note: Authority G.S. 90-85.6; 90-85.15;

PENNSYLVANIA

PROPOSED RULEMAKING

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Technology and Automation

[34 Pa.B. 3146]

The State Board of Pharmacy (Board) proposes to amend §§ 27.1 and 27.14 (relating to definitions; and supplies) and to add §§ 27.201--27.204 (relating to technology and automation) to read as set forth in Annex A.

Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

The proposed rulemaking is authorized under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (63 P. S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Background and Purpose

The use of computer-based information and communications systems are now prevalent in the fields of medicine and pharmacy. Current regulations of the Board do not reflect nor regulate the use of this technology. The proposed rulemaking allows the incorporation of this technology into the practice of pharmacy and brings the Commonwealth up to date with regulations of other states that currently regulate this technology. The purpose of the proposed rulemaking is to set standards for the use of this technology.

Currently, the Board's regulations do not govern whether pharmacies may accept the transmission of prescriptions of a lawful prescriber by electronic means. Prescriptions may be sent to the pharmacy by telephone or facsimile under §§ 27.18(n) and 27.20 (relating to standards of practice; and facsimile machines). The proposed rulemaking allows pharmacies to accept a prescription that was transmitted electronically through the Internet or intranet. Pharmacies would also be permitted to maintain the prescription electronically, thus eliminating a need to maintain an original paper prescription. The proposed rulemaking also allows pharmacies to maintain required records on a computer as opposed to keeping paper files. Pharmacies can then begin moving toward a paperless recordkeeping system.

The proposed rulemaking also provides for the use of centralized prescription processing and automated medication systems. By implementing these innovations into the practice of pharmacy, a pharmacist may spend more time dealing with the clinical aspects of the practice of pharmacy.

Description of the Proposed Rulemaking

Section 27.14(c)(11) permits the use of a computerized recordkeeping system in a pharmacy and lists two standards for the use of a computerized recordkeeping system. Proposed § 27.202 (relating to computerized recordkeeping systems) provides a more comprehensive set of standards for a pharmacy's use of a computerized recordkeeping system. Therefore, the proposed amendment to § 27.14(c)(11) removes standards for computerized recordkeeping to the extent they are under proposed § 27.202 and instead cross references § 27.202. The Board also proposes to amend § 27.14 to remove the direct reference to 21 CFR 1304.04(h) (relating to maintenance of records and inventories) and replace that language with a broader reference to State and Federal laws and regulations. The Board recognizes that 21 CFR 1304.04(h) is not the only law or regulation that governs controlled substance prescription records. The proposed rulemaking is more accurate with regard to the duty of a pharmacy to maintain records in accordance with both State and Federal law.

Proposed § 27.201 (relating to electronically transmitted prescriptions) regulates prescriptions transmitted to a pharmacy by electronic means. Currently, the regulations allow for a pharmacist to accept prescriptions transmitted through the telephone or a facsimile machine, but they do not address the acceptance of prescriptions transmitted through electronic means such as a computer or palm device. The proposed rulemaking sets forth the requirements of the electronic prescription that a pharmacist may accept. To protect the prescription from being altered, it must be electronically encrypted or protected by some other means to prevent access, alteration, manipulation or use by an unauthorized person. The patient is able to choose the pharmacy where the prescription will be transmitted. If a pharmacist believes that the prescription does not comply with State and Federal Law, the pharmacist may choose not to fill the prescription. This section also sets forth the recordkeeping requirements for electronic prescriptions. The regulation requires that either a hard copy or a readily retrievable image must be kept for at least 2 years from the date of the most recent filling of the prescription. This 2-year time frame mirrors the length of time that paper prescriptions are required to be kept on file. Like the existing regulations dealing with facsimile machines, this section prohibits any pharmacy or pharmacist from supplying electronic equipment to any prescriber for transmitting prescriptions. Additionally, the proposed rulemaking clarifies that as an electronic transaction, the transmittal of a prescription through electronic means would also be governed by the Electronic Transactions Act (73 P. S. §§ 2260.101--2260.5101).

Proposed § 27.202 provides standards for maintaining records on a computer as opposed to keeping paper files. The records must be immediately retrievable for prescriptions filled within the previous 12 months or retrievable within 3 working days for prescriptions filled within the previous 24 months. The Board feels that these timeframes are reasonable and will not adversely affect patient care. The proposed rulemaking sets forth the information that must be retrievable. Information that is currently required to be on prescriptions under § 27.18(b)(1), as well as identification of the pharmacist responsible for prescription information entered into the computer system, must be retrievable. This section also provides the procedures to be followed when the system experiences down time. To ensure

patient safety, prescription information must be entered into the computerized recordkeeping system as soon as it is available for use. Furthermore, when the information from the computerized recordkeeping system is not available, prescriptions may only be refilled if the number of refills authorized by the prescriber has not been exceeded. Finally, safeguards must be in place to prevent access by unauthorized individuals and to identify any modification or manipulation of information in the system.

Proposed § 27.203 (relating to centralized prescription processing) sets forth the standards applicable to centralized prescription processing. Centralized prescription processing is a process where a prescription is tendered to one pharmacy (the proposed rulemaking calls it the "originating pharmacy"), then transmitted to a central fill pharmacy where the prescription is filled or refilled. Generally, given the volume of prescriptions that it fills, the central fill pharmacy uses an automated medication system to fill prescriptions. The filled prescription is then transferred to the delivering pharmacy where the filled prescription is ultimately delivered to the patient. This section sets forth definitions for each pharmacy involved in centralized prescription processing and specifies which pharmacy is responsible for each step in the prescription filling process. The Board has determined that because a central processing center may be considered the "originating pharmacy" as defined by this section, the central processing center must also be a licensed pharmacy. Because the Board understands that the primary focus of the central processing center will be to process prescriptions and not actually dispense them, the Board has decided to exempt the central processing center from the requirement to maintain \$5,000 worth of nonproprietary drugs and devices in § 27.14(a).

Proposed § 27.204 (relating to automated medication systems) regulates the use of automated medication systems to fill prescriptions. This section defines an automated medication system and sets forth the requirements and safeguards that must be in place to use a system such as this. Automated medication systems may be used either in a licensed pharmacy or offsite as long as the operation of the automated medication system is supervised by a pharmacist. The proposed rulemaking requires that automated medication systems be validated to accurately dispense medication prior to going into use. The proposed rulemaking also requires an audit trail of the activity of each pharmacist, technician or other authorized personnel working on the automated medication system. The Board may inspect the system to further validate the accuracy of the system. This section sets forth a comprehensive list of requirements pertaining to policies and procedures in operating these systems, conducting maintenance and in the case of disaster. The proposed rulemaking requires written policies and procedures of operation, quality assurance programs, plans for recovery from disaster and preventative maintenance.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking has no fiscal impact, nor would it impose any additional paperwork requirement on the Commonwealth. The proposed rulemaking should alleviate some paperwork requirements on the regulated community.

Sunset Date

The Board reviews the effectiveness of its regulations on an ongoing basis. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 8, 2004, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Melanie Zimmerman, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

RICHARD R. SIGMA, R.Ph.,
Chairperson

Fiscal Note: 16A-5410. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

GENERAL PROVISIONS

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Automated medication system--

(i) A process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls and maintains all transaction information.

(ii) The term does not mean an automatic counting device.

* * * * *

Central fill pharmacy--A pharmacy engaging in centralized prescription processing by filling and refilling prescriptions, which includes the preparation and packaging of the medication.

Centralized prescription processing--The processing, under the direction of a pharmacist, of a request to fill or refill a prescription, to perform functions such as refill authorizations, interventions or other matters related to the practice of pharmacy for subsequent delivery to the delivering pharmacy.

Central processing center--A pharmacy operated under the direction of a pharmacist that engages solely in centralized prescription processing.

* * * * *

Delivering pharmacy--The pharmacy that receives the processed prescription or the filled or refilled prescription for delivering to the patient or the patient's authorized representative.

* * * * *

Originating pharmacy--The pharmacy that receives the patient's or prescribing practitioner's request to fill or refill a prescription and performs functions such as the prospective drug review. The central processing center or the central fill pharmacy may be considered the originating pharmacy if the prescription was transmitted by the prescriber directly to the centralized pharmacy or if the patient requested the refill from that pharmacy.

* * * * *

STANDARDS

§ 27.14. Supplies.

* * * * *

(c) A pharmacy shall maintain at least the following equipment and supplies:

* * * * *

(11) Prescription files for keeping prescriptions of nonproprietary drugs in accordance with the act and, for controlled substance prescriptions, [the regulations of the DEA in 21

CFR 1304.04(h) (relating to maintenance of records and inventories)] State and Federal laws and regulations. The original prescription or image of the original prescription shall be retained for 2 years from the date of the most recent filling. A pharmacy may make use of a computerized recordkeeping system for keeping track of telephone prescriptions, refills, counseling, and the like[, if the system has safeguards to prevent accidental erasure and the information can be transferred to hard copy within 72 hours] in accordance with § 27.202 (relating to computerized recordkeeping systems).

* * * * *

TECHNOLOGY AND AUTOMATION

§ 27.201. Electronically transmitted prescriptions.

(a) For the purposes of this section, an electronically transmitted prescription means the communication to the pharmacist by means of data base exchange or e-mail (which does not include telephone or facsimile machine) of original prescriptions or refill authorizations, which have been sent directly from an authorized licensed prescriber or an authorized agent to the pharmacy of the patient's choice and which have not been altered, accessed, viewed, screened or manipulated by an intervening entity or person unless authorized by law.

(b) Except for Schedule II controlled substances which must conform to § 27.18(b)(2) (relating to standards of practice), a pharmacist may accept an electronically transmitted prescription, from a prescriber or a designated agent which has been sent directly to a pharmacy of the patient's choice if the following requirements are met:

(1) The prescription must contain the signature or the electronic equivalent of a signature of the prescriber made in accordance with the Electronic Transactions Act (73 P. S. §§ 2260.101--2260.5101).

(2) The prescription must include the following information:

(i) The information that is required to be contained on a prescription under State and Federal law.

(ii) The prescriber's telephone number.

(iii) The date of the transmission.

(iv) The name of the pharmacy intended to receive the transmission.

(3) The prescription must be electronically encrypted or transmitted by other technological means designed to protect and prevent access, alteration, manipulation or use by any unauthorized person.

(4) A hard copy or a readily retrievable image of the prescription information that is transmitted must be stored for at least 2 years from the date of the most recent filling.

(5) An electronically transmitted prescription must be processed in accordance with the act and this chapter.

(c) The pharmacist and pharmacy may not provide electronic equipment to a prescriber for the purpose of transmitting prescriptions.

§ 27.202. Computerized recordkeeping systems.

(a) A computerized system used by a pharmacy for recording and maintaining information concerning prescriptions under State and Federal laws must be designed so that it is capable of providing immediate retrieval (by means of monitor, hard-copy printout or other transfer medium) of patient information for all prescriptions filled within the previous 12 months and retrieval within 3 working days of all prescriptions dispensed within the previous 24 months from the last activity date. This information must include the following data:

(1) The information required to be on prescriptions under § 27.18(b)(1) (relating to standards of practice).

(2) Identification of the pharmacist responsible for prescription information entered into the computer system.

(b) The system must be able to transfer all patient information to hard copy within 3 working days.

(c) Prescriptions entered into a computer system but not immediately dispensed must meet the following conditions:

(1) The complete prescription information must be entered in the computer system.

(2) The information must appear in the patient's profile.

(3) There must be positive identification, in the computer system or on the hard-copy prescription, of the pharmacist who is responsible for entry of the prescription information into the system.

(4) The original prescription must be filed according to § 27.18(b).

(d) If the computerized recordkeeping system experiences down time, the prescription information must be entered into the computerized recordkeeping system as soon as it is available for use. During the time the computerized recordkeeping system is not available, prescriptions may be refilled only if the number of refills authorized by the prescriber has not been exceeded.

(e) The system must have adequate safeguards to:

(1) Prevent access by any person who is not authorized to obtain information from the system.

(2) Identify any modification or manipulation of information concerning a prescription.

- (3) Prevent accidental erasure of information.

§ 27.203. Centralized prescription processing.

(a) *Centralized prescription processing.* A central fill pharmacy or central processing center may fulfill a request for the processing, filling or refilling of a prescription from either the originating pharmacy or from the patient or the prescriber and may deliver the processed, filled or refilled prescription to a delivering pharmacy provided:

(1) The central fill pharmacy or the central processing center that is to process, fill or refill the prescription has a contract with or has the same owner as the originating pharmacy and the delivering pharmacy. Contractual provisions must include confidentiality of patient information.

(2) The prescription container:

(i) Is clearly labeled with the information required by Federal and State laws and regulations.

(ii) Clearly shows the name, address, telephone number and DEA number of the delivering pharmacy.

(3) Pharmacies that either utilize or act as central fill pharmacies or central processing centers shall have policies and procedures in place that include an audit trail that records and documents the central prescription process and the individuals accountable at each step in the process for complying with Federal and State laws and regulations including recordkeeping.

(4) Pharmacies that engage in centralized prescription processing share a common electronic file.

(5) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.

(6) The delivering pharmacy is responsible for making the offer to counsel to the patient under § 27.19(e) (relating to prospective drug review and patient counseling).

(b) *Exemption.* The central processing center is exempt from maintaining an inventory of at least \$5,000 worth of nonproprietary drugs and devices under § 27.14(a) (relating to supplies).

§ 27.204. Automated medication systems.

(a) This section establishes standards applicable to licensed pharmacies that utilize automated medication systems which may be used to store, package, dispense or distribute prescriptions.

(b) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

(1) The pharmacist manager, or the pharmacist under contract with a long-term care facility responsible for the dispensing of medications if an automated medication system is utilized at a location which does not have a pharmacy onsite, is responsible for the supervision of the operation of the system.

(2) The automated medication system has been tested and validated by the pharmacy and found to dispense accurately prior to the implementation of the system. The pharmacy shall make the results of the testing available to the Board upon request.

(3) The pharmacy shall make the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(4) The automated medication system shall electronically record the activity of each pharmacist, technician or other authorized personnel with the time, date and initials or other identifier in a manner that a clear, readily retrievable audit trail is established. It is the intent of this section to hold responsible each pharmacist for the transaction performed by that pharmacist, precluding the need for a final check of a prescription by one individual pharmacist prior to delivery.

(c) The pharmacist manager or the pharmacist under contract with a long-term care facility responsible for the delivery of medications shall be responsible for the following:

(1) Reviewing and approving the policies and procedures for system operation, safety, security, accuracy, access and patient confidentiality.

(2) Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability.

(3) Assigning, discontinuing or changing personnel access to the automated medication system.

(4) Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(5) Ensuring compliance with applicable provisions of State and Federal law.

(d) When an automated medication system is used to fill prescriptions or medication orders, it must be operated according to written policies and procedures of operation. The policies and procedures of operation must:

(1) Include a table of contents.

(2) Include a description of all procedures of operation.

(3) Set forth methods that shall ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least 2 years after the change is made. Each change shall be signed or initialed by the registered pharmacist in charge and include the date on which the registered pharmacist in charge approved the change.

(4) Set forth methods that ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made.

(5) Set forth methods that ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records.

(6) Set forth methods that ensure that access to the automated medication system for stocking and removal of medications is limited to licensed pharmacists or qualified support personnel acting under the supervision of a licensed pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system must be maintained.

(7) Identify the circumstances under which medications may be removed from the automated medication system by a licensed medical practitioner for distribution to a patient without prior order review by a licensed pharmacist.

(e) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them, if necessary.

(f) A copy of the written policies and procedures of operation adopted under this section shall be retained at the pharmacy and at the long-term care facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

(g) The pharmacist manager shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and supportive personnel are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures. The training shall be documented and available for inspection.

(h) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system which:

(1) Requires monitoring of the automated medication system.

(2) Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every 6 months and whenever any upgrade or change is made to the system.

(3) Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least 2 years. Upon reasonable notice from the Board, the pharmacy shall provide information to the Board regarding the quality assurance program for automated medication systems.

(i) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster that interrupts

the ability of the pharmacy to provide services. The written plan for recovery must include:

- (1) Planning and preparation for a disaster.
- (2) Procedures for response to a disaster.
- (3) Procedures for the maintenance and testing of the written plan for recovery.

(j) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system. Documentation of completion of all maintenance shall be kept on file in the pharmacy for a minimum of 2 years.

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TITLE 22

EXAMINING BOARDS

PART 15

TEXAS STATE BOARD OF PHARMACY

CHAPTER 291

PHARMACIES

SUBCHAPTER B

COMMUNITY PHARMACY (CLASS A)

RULE §291.38

Central Prescription Drug or Medication Order Processing

(a) Purpose.

(1) The purpose of this section is to provide standards for centralized prescription drug or medication order processing by a Class A (Community), Class C (Institutional), or Class E (Non-Resident) pharmacy.

(2) Any facility established for the purpose of processing prescription drug or medication drug orders shall be licensed as a Class A pharmacy under the Act. However, nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in Texas from remotely accessing the pharmacy's electronic data base from outside the pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act.

(1) Act The Texas Pharmacy Act, Chapters 551 - 566, Occupations Code, as amended.

(2) Centralized prescription drug or medication order processing The processing of a prescription drug or medication orders by a Class A, Class C, or Class E pharmacy on behalf of another pharmacy, a health care provider, or a payor. Centralized prescription drug or medication order processing does not include the dispensing of a prescription drug order but includes any of the following:

(A) receiving, interpreting, or clarifying prescription drug or medication drug orders;

(B) data entering and transferring of prescription drug or medication order information;

(C) performing drug regimen review;

(D) obtaining refill and substitution authorizations;

(E) interpreting clinical data for prior authorization for dispensing;

(F) performing therapeutic interventions; and

(G) providing drug information concerning a patient's prescription.

(3) Dispense Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful

order of a practitioner.

(4) Drug regimen review An evaluation of prescription drug or medication orders and patient medication records for:

- (A) known allergies;
- (B) rational therapy-contraindications;
- (C) reasonable dose and route of administration;
- (D) reasonable directions for use;
- (E) duplication of therapy;
- (F) drug-drug interactions;
- (G) drug-food interactions;
- (H) drug-disease interactions;
- (I) adverse drug reactions; and
- (J) proper utilization, including overutilization or underutilization.

(5) Patient counseling Communication by the pharmacist of information to the patient or patient's agent in order to improve therapy by ensuring proper use of drugs and devices.

(c) Operational Standards.

(1) General requirements.

(A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication order processing to another Class A, Class C, or Class E pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

(II) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function.

(B) A pharmacy that performs centralized prescription drug or medication order processing shall comply with the provisions applicable to the class of pharmacy contained in either §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Triplicate Prescription

Requirements in Class A (Community) Pharmacies), or §§291.71 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class C (Institutional) Pharmacy), or §§291.101 - 291.105 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident) Pharmacy) to the extent applicable for the specific processing activity and this section including:

- (i) duties which must be performed by a pharmacist; and
- (ii) supervision requirements for pharmacy technicians.

(2) Notifications to patients.

(A) A pharmacy that outsources prescription drug or medication order processing to another pharmacy shall prior to outsourcing their prescription:

- (i) notify patients that prescription processing may be outsourced to another pharmacy; and
- (ii) give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

(B) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., hospitals or nursing homes).

(3) Policy and Procedures. A policy and procedure manual as it relates to central processing shall be maintained at all pharmacies involved in central processing and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

- (A) outline the responsibilities of each of the pharmacies;
- (B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription drug or medication order processing; and
- (C) include policies and procedures for:
 - (i) protecting the confidentiality and integrity of patient information;
 - (ii) maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing;
 - (iii) complying with federal and state laws and regulations;
 - (iv) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(v) annually reviewing the written policies and procedures and documenting such review.

(d) Records. All pharmacies shall maintain appropriate records which identify, by prescription drug or medication order, the name(s), initials, or identification code(s) of each pharmacist or pharmacy technician who performs a processing function for a prescription drug or medication order. Such records may be maintained:

(1) separately by each pharmacy and pharmacist; or

(2) in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

Source Note: The provisions of this §291.38 adopted to be effective December 15, 2002, 27 TexReg 11539

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VIRGINIA

BOARD OF PHARMACY
18VAC110-20-10 et seq.

PROPOSED REGULATIONS ON OUTSOURCING PRESCRIPTION PROCESSING
(Public comment from 1/10/05 to 3/11/05)

18VAC110-20-276. Central or remote processing.

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
6. Interpreting clinical data for prior authorization for dispensing;
7. Performing therapeutic interventions; or
8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
2. Any central or remote pharmacy shall comply with Virginia law with respect to duties which are restricted to pharmacists and pharmacy technicians must be directly supervised by a pharmacist;
3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and
4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of

Proposed Regulations on Outsourcing

any contract pharmacy providing central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;
3. Procedures for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations to include counseling;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.
2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.

A. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;

3. Transferring prescription information;

4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication;

5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order;

6. Interpreting or acting on clinical data;

7. Performing therapeutic interventions;

8. Providing drug information to the medical or nursing staff of the hospital or long term care facility; or

9. Authorizing the administration of the drug to the patient by appropriate hospital or long term care facility staff.

B. The primary pharmacy providing pharmacy services to a hospital or long term care facility may outsource certain order processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;

2. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist and the remote pharmacy shall comply with Virginia law with respect to duties which are restricted to pharmacists and supervision requirements for pharmacy technicians;

3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and

4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a prescription order.

C. A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;

2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;

3. Procedures for protecting the confidentiality and integrity of patient information;

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

5. Procedures for maintaining required records;

6. Procedures for complying with all applicable laws and regulations;

7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and

8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

D. A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.

1. The record shall be available by prescription order or by patient name.

2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.

3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

E. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

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Chapter Phar 7

PHARMACY PRACTICE

Phar 7.01	Minimum procedures for compounding and dispensing.
Phar 7.015	Pharmacy technicians.
Phar 7.02	Prescription label; name of drug or drug product dispensed.
Phar 7.03	Prescription renewal limitations.
Phar 7.04	Return or exchange of health items.
Phar 7.05	Prescription records.

Phar 7.065	Answering machines in pharmacies.
Phar 7.07	Medication profile record system.
Phar 7.08	Prescription orders transmitted electronically.
Phar 7.09	Automated dispensing systems.
Phar 7.10	Administration of drug products and devices other than vaccines.
Phar 7.12	Central fill pharmacy.

Phar 7.01 Minimum procedures for compounding and dispensing. (1) Except as provided in sub. (4), a pharmacist or pharmacist-intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist-intern as directed and supervised by a pharmacist shall:

(a) Receive electronic or oral prescription orders of a prescriber, review all original and renewal prescription orders, whether electronic, written or oral, and determine therapeutic compatibility and legality of the prescription order. The review shall include, when indicated or appropriate, consultation with the prescriber.

(b) Read and interpret a prescriber's directions for use for the purpose of accurately transferring the instructions to the prescription label.

(c) Select, compound, mix, combine, measure, count and otherwise prepare drugs needed to dispense a prescription except that an agent of the pharmacist may procure, measure or count prefabricated dosage forms if a pharmacist verifies accuracy of the agent's action.

(d) Make a final check on the accuracy and correctness of the prescription. For all original and renewed prescriptions, the prescription order record shall identify the pharmacist responsible for the prescription.

(e) Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a patient's residence, is not satisfied by only offering to provide consultation.

(em) Transfer the prescription to the patient or agent of the patient.

(f) Receive, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on the prescription order, medication profile record or uniformly maintained and readily retrievable document the following information:

1. Date renewed.
2. Name of practitioner authorizing renewal, if different from the original prescriber.
3. Quantity of drug dispensed.
4. Identification of the pharmacist renewing the prescription.

(2) Subsection (1) (d) and (e) does not prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. Subsection (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharged patients.

(3) A pharmacist may supervise no more than one pharmacy intern and 4 pharmacy technicians engaged in compounding and dispensing activities as described in sub. (1), except a higher ratio

may be authorized by the board upon request to and approval by the board of a specific plan describing the manner in which additional interns or pharmacy technicians shall be supervised.

(4) A system for compounding and dispensing not in conformance with subs. (1) to (3) may be used if reviewed and approved by the board.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (1) (intro.), (d) and (f) (intro.), Register, August, 1991, No. 428, eff. 9-1-91; am. (1) (e), Register, January, 1996, No. 481, eff. 2-1-96; am. (1) (a), (e), (f) (intro.), (3) and cr. (1) (em), Register, December, 1998, No. 516, eff. 1-1-99; am. (1) (a), Register, November, 1999, No. 527, eff. 12-1-99; am. (3), Register, April, 2001, No. 544, eff. 5-1-01.

Phar 7.015 Pharmacy technicians. (1) As used in this section, "pharmacy technician" means a non-pharmacist or non-pharmacist intern who, under the general supervision of a pharmacist who regularly coordinates, directs and inspects the activities of the pharmacy technician, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescription orders and inventory management. "Pharmacy technician" does not include ancillary persons which include, clerks, secretaries, cashiers or delivery persons, who may be present in the pharmacy.

(2) A pharmacist may delegate technical dispensing functions to a pharmacy technician, but only under the general supervision of the pharmacist where the delegated functions are performed. Technical dispensing functions include:

(a) Accepting written or electronic prescription orders of the prescribing practitioner or from the prescribing practitioner's agent.

(b) Accepting original oral prescription orders from the prescribing practitioner or prescribing practitioner's agent, if the conversation is recorded and listened to and verified by the pharmacist prior to dispensing.

(c) Requesting authorization for a refill from the prescribing practitioner.

(d) Accepting oral authorization for a refill from the prescribing practitioner or prescribing practitioner's agent, provided there are no changes to the original prescription order.

(e) Accepting a request from a patient to refill a prescription.

(f) Obtaining and entering patient or prescription data into the patient information system.

(g) Preparing a prescription label.

(h) Retrieving medication from stock, counting or measuring medication, and placing the medication in its final container.

(i) Reconstituting prefabricated dosage forms.

(j) Compounding pharmaceuticals pursuant to written policies and procedures.

(k) Affixing a prescription label to its final container.

(L) Placing ancillary information on the prescription label.

(m) Prepackaging and labeling drugs for dispensing by a pharmacist.

(n) Preparing unit dose carts for final review by a pharmacist.

(o) Retrieving and transporting stock medication to and from pharmacist approved areas.

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(p) Other technical functions that do not require the professional judgment of a pharmacist.

(3) A pharmacy technician may not do any of the following:

(a) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(b) Perform any of the following tasks:

1. Participate in final drug utilization reviews.

2. Make independent therapeutic alternate drug selections.

3. Participate in final drug regimen screening, including screening for therapeutic duplication, drug-to-drug interactions, incorrect dosage, incorrect duration of treatment, drug allergy reactions and clinical abuse or misuse.

4. Perform any act necessary to be a managing pharmacist.

5. Administer any prescribed drug products, devices or vaccines.

(c) Provide patient counseling, consultation, or patient specific judgment, such as interpreting or applying information, including advice relating to therapeutic values, potential hazards and uses.

(d) Transfer the prescription to the patient or agent of the patient.

(4) The pharmacist shall provide the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative.

History: Cr. Register, April, 2001, No. 544, eff. 5-1-01.

Phar 7.02 Prescription label; name of drug or drug product dispensed. No prescription drug may be dispensed unless the prescription label discloses the brand name and strength, or the generic name, strength, and manufacturer or distributor of the drug or drug product dispensed unless the prescribing practitioner requests omission of the above information. The prescription label shall not contain the brand or generic name of any drug or drug product other than that actually dispensed.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; Register, August, 1991, No. 428, eff. 9-1-91; am. Register, January, 1996, No. 481, eff. 2-1-96.

Phar 7.03 Prescription renewal limitations. A prescription order for any drug other than controlled substances, which bears renewal authorization permitting the pharmacist to renew the prescription as needed (PRN) by the patient, shall not be renewed beyond one year from the date originally prescribed. No prescription order containing either specific or PRN renewal authorization is valid after the patient-physician relationship has ceased.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; Register, August, 1991, No. 428, eff. 9-1-91.

Phar 7.04 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned, except for any of the following:

(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

(b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their expiration date.

(c) When in the professional judgment of the pharmacist substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient's family or agent, or other person.

(3) Health items returned to a pharmacy pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(4) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient's use.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; r. and recr., Register, December, 1998, No. 516, eff. 1-1-99.

Phar 7.05 Prescription records. (1) A record of all prescriptions dispensed shall be maintained for a period of 5 years after the date of the last renewal.

(2) All systems used for maintaining a record of any prescription dispensing shall include:

(a) Patient's identification.

(b) Name, strength and dosage form of the drug product dispensed.

(c) Quantity dispensed.

(d) Date of all instances of dispensing.

(e) Practitioner's identification.

(f) Pharmacist's identification.

(g) Retrieval designation.

(3) (a) Except as provided in sub. (5), the transfer of prescription order information for the purpose of dispensing is permissible between pharmacies on an unlimited basis pursuant to the following requirements:

1. The transfer is communicated directly between 2 pharmacists and the pharmacist making the transfer records the following information:

a. The word "VOID" is written on the face of the invalidated prescription order.

b. The name and address of the pharmacy to which it is transferred, the name of the pharmacist receiving the prescription order, the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

(b) The pharmacist receiving the transferred prescription order information shall record in writing the following:

1. The word "TRANSFER" on the face of the transferred prescription order.

2. The date of issuance of the original prescription order.

3. The original number of renewals authorized on the original prescription order.

5. The number of valid renewals remaining and the date of the last renewal.

6. The pharmacy's name, address, and the prescription order number from which the prescription order information was transferred.

7. The name of the pharmacist making the transfer.

8. The name, address and telephone number of the pharmacy from which the original prescription order was transferred if different from subd. 6.

(c) The original and transferred prescription orders shall be maintained for a period of 5 years from the date of the last renewal.

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(4) A written copy of any prescription order for a prescribed drug provided by a pharmacist shall be identified in writing as "COPY — FOR INFORMATION ONLY". No prescribed drug may be dispensed based on an information copy.

(5) The transfer of original prescription order information for the purpose of renewal dispensing of a controlled substance is permissible between 2 pharmacies only on a one-time basis. However, pharmacies having access to a common central processing unit are not limited in the transfer of original prescription order information pertaining to controlled substances for the purpose of renewal dispensing if prior written approval is received from the board.

Note: This procedure requires a variance from the federal drug enforcement administration (DEA) for controlled substances. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537.

(6) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purposes of renewal dispensing, if the system:

(a) Is capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining. The system shall be designed so that the pharmacy can receive the printout within 48 hours after requesting the printout.

(b) Is equipped with an auxiliary procedure which, during periods of down-time, shall be used for documentation of prescription dispensing. The auxiliary procedure shall ensure that prescription renewals are authorized by the original prescription order, that the maximum number of prescription renewals has not been exceeded and that all of the appropriate data are retained for on-line entry as soon as the computer system is again available for use.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; cr. (5), Register, September, 1987, No. 381, eff. 10-1-87; CR 00-165: am. (3) (a) (intro.), (b) 6., (c), (5) and (6) (intro.), r. (3) (b) 4., cr. (3) (b) 8., Register July 2001, No. 547 eff. 8-1-01.

Phar 7.065 Answering machines in pharmacies.

Oral prescription orders may be received at a pharmacy via a telephone answering device and dispensed by the pharmacist if the voice of the physician or physician's agent is known to the pharmacist, and provided other requirements of reducing the prescription order to writing, labeling and filing are met.

History: Cr. Register, December, 1998, No. 516, eff. 1-1-99.

Phar 7.07 Medication profile record system. (1) An individual medication profile record system shall be maintained in all pharmacies for persons for whom prescriptions, original or renewal, are dispensed for outpatient use. The system shall be capable of permitting the retrieval of information. The system need not be limited to individual medication profile records.

(2) The following minimum information shall be retrievable:

- (a) Patient name, or other identifying information.
- (b) Address of the patient.
- (c) Birth date of the patient if obtainable.
- (d) Name of the drug product dispensed.
- (e) Strength of the drug product dispensed.
- (f) Dosage form of the drug product dispensed.
- (g) Quantity of the drug product dispensed.
- (h) Directions for use.
- (i) Retrieval designation assigned to the prescription order.
- (j) Date of all instances of dispensing, for original and renewal prescriptions.

(k) Practitioner identification.

Note: This subsection incorporates renewal dispensing information required by federal law (21 CFR 1306.22) and state law (s. 450.11 (5), Stats.).

(3) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(4) At the time a prescription order is reviewed by the pharmacist for dispensing, the pharmacist shall review the medication profile record of the patient for the previously dispensed medication history and shall determine whether the prescription order presented should be dispensed.

(5) Medication profile records, if used as the only documentation of renewal dispensing, shall be maintained for a period of not less than 5 years following the date of the last entry. If the profile records are not used as the only documentation of renewal dispensing they shall be maintained for a period of not less than 1 year from the date of the last entry.

History: Cr. Register, January, 1989, No. 397, eff. 2-1-89; renum. from Phar 7.08, Register, August, 1991, No. 428, eff. 9-1-91; am. (1), Register, December, 1998, No. 516, eff. 1-1-99.

Phar 7.08 Prescription orders transmitted electronically. (1) Except as provided in s. 453.068 (1) (c) 4., Stats., and as otherwise prohibited by law, prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device.

Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

Note: Prescription orders for schedule II controlled substances may not be transmitted electronically except as emergency orders, subject to the same requirements for oral emergency orders for schedule II controlled substances. See s. 961.38 (1r) and (2), Stats., and s. Phar 8.09.

(2) A pharmacist may dispense a prescription pursuant to a prescription order transmitted electronically, if the pharmacist assures the prescription order does all of the following:

(a) Was sent only to the pharmacy of the patient's choice and only at the option of the patient, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.

(b) Identifies the individual sender's name and telephone number for oral confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission.

(c) Is designated "electronically transmitted prescription", or with similar words or abbreviations to that effect.

(d) Contains all other information that is required in a prescription order.

(3) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided with a prescription order electronically transmitted via computer modem or other similar electronic device.

(4) Any visual or electronic document received in connection with an electronically transmitted prescription order shall be accessible only within the professional service area of the pharmacy to protect patient confidentiality and assure security.

(5) A pharmacist who receives a prescription order electronically shall ensure the security, integrity and confidentiality of the prescription order and any information contained in the order. To maintain the confidentiality of patient records, the electronic system shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the prescription has been dispensed, any alterations in prescription order drug data shall be documented including the identification of the pharmacist responsible for the alteration.

(6) Access to the electronic mail system for the receipt of prescription orders electronically may only be acquired by use of a password or passwords, known only to individuals authorized to access the system.

(7) A pharmacist may not use any electronic device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying prescription orders or in order to circumvent other pharmacy laws.

History: Cr. Register, November, 1999, No. 527, eff. 12-1-99.

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Phar 7.09 Automated dispensing systems. (1) In this section:

(a) "Automated dispensing system" means a mechanical system that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, or tuberculosis sanatorium, but does not include community-based residential facilities.

(2) An automated dispensing system may be used in a community pharmacy, as provided in this section.

(3) An automated dispensing system may be used as provided in this section by an institutional pharmacy serving an inpatient health care facility, that has an established program of receiving prescription orders, and dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. An automated dispensing system used by an institutional pharmacy shall only be located in that institutional pharmacy or within the inpatient health care facility.

(4) The managing pharmacist of a community pharmacy or an institutional pharmacy is responsible for all of the following:

(a) Assuring that the automated dispensing system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed and complying with the recordkeeping and security safeguards pursuant to sub. (5).

(b) Implementing an ongoing quality assurance program that monitors performance of the automated dispensing system, which is evidenced by written policies and procedures.

(c) Providing the board with prior written notice of the installation or removal of an automated dispensing system. The notice provided shall include, but is not limited to the:

1. Name and address of the pharmacy.

2. Initial location of the automated dispensing system. The automated dispensing system may thereafter be relocated within the pharmacy or inpatient health care facility without providing subsequent notification to the board.

3. Identification of the managing pharmacist.

(d) Assigning, discontinuing or changing personnel access to the system.

(e) Assuring that access to the medications comply with state and federal laws.

(f) Assuring that the automated dispensing system is stocked accurately and in accordance with established written policies and procedures.

(5) An automated dispensing system shall comply with the following provisions:

(a) A pharmacy shall maintain on-site the following documentation relating to an automated dispensing system:

1. Name and address of the pharmacy or inpatient health care facility where the system is being used.

2. The system manufacturer's name, model and serial number.

3. Description of how the system is used.

4. Written quality assurance procedures to determine continued appropriate use of the system.

5. Except as required pursuant to par. (b), written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

(b) All written policies and procedures shall be maintained in the pharmacy responsible for the automated dispensing system.

(c) An automated dispensing system shall have adequate security systems and procedures, evidenced by written policies and

procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

(d) Records and data kept by the automated dispensing system shall meet the following requirements:

1. All events involving the contents of the automated dispensing systems must be recorded electronically.

2. Records shall be maintained by the pharmacy and be available to the board. Records shall include:

a. The time and location of the system accessed.

b. Identification of the individual accessing the system.

c. Type of transaction.

d. Name, strength, dosage form and quantity of the drug accessed.

e. Name of the patient for whom the drug was ordered.

f. Such additional information as the managing pharmacist may deem necessary.

(e) The stocking of all medications in the automated dispensing system shall be accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an automated dispensing system is located within a pharmacy the supervision must be direct.

(f) A record of medications stocked into an automated dispensing system shall be maintained for 5 years and shall include identification of the person stocking and pharmacist checking for accuracy.

(g) All containers of medications stored in the automated dispensing system shall be packaged and labeled in accordance with state and federal law.

(h) All aspects of handling controlled substances shall meet the requirements of all state and federal law.

(i) The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system, in accordance with state and federal law.

(j) The automated dispensing system shall provide a mechanism for securing and accounting for medication returned to the system and accounting for wasted medications in accordance with state and federal law.

History: Cr. Register, October, 2000, No. 538, eff. 11-1-00.

Phar 7.10 Administration of drug products and devices other than vaccines. A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats., in the course of teaching a patient self-administration techniques except a pharmacist may not administer by injection a prescribed drug product or device unless he or she satisfies each of the following:

(1) The pharmacist has successfully completed 12 hours in a course of study and training, approved by the American council on pharmaceutical education or the board, in injection techniques, emergency procedures and record keeping.

(2) The pharmacist has in effect liability insurance against loss, expense and liability resulting from errors, omissions or neglect in the administration by injection of prescribed drug products or devices in an amount that is not less than \$1,000,000 for each occurrence and \$2,000,000 for all occurrences in any one policy year. The pharmacist shall maintain proof that he or she satisfies this requirement and, upon request, shall provide copies of such proof to the department or board.

(3) The pharmacist has written procedures regarding the administration by injection of a prescribed drug product or device in the course of teaching self-administration techniques to a patient.

Note: To administer a vaccine a pharmacist must meet the requirements in s. 450.035, Stats.

History: Cr. Register, December, 1999, No. 528, eff. 1-1-00.

Unofficial Text (See Printed Volume). Current through date and Register shown on Title Page.**Phar 7.12 Central fill pharmacy. (1)** In this section:

(a) "Central fill pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

(b) "Originating pharmacy" means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

(2) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:

(a) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

(b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the board or its agent.

(c) The central fill pharmacy and originating pharmacy maintain a written filling protocol delineating each pharmacy's assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8.

(d) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8, and which are not assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

(e) The originating pharmacy shall at all times remain solely responsible to perform and comply with the requirements of s. Phar 7.01 (1) (e) and (em).

(f) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review of the patient, drug initialization review, refill authorizations, interventions and drug interactions.

(g) The prescription label attached to the container shall contain the name and address of the originating pharmacy as the licensed facility from which the prescribed drug or device was dispensed for purposes of s. 450.11 (4) (a) 1., Stats. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the central fill pharmacy filled the prescription order.

(h) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

(i) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law.

(j) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding and dispensing pursuant to a prescription order and track the prescription order during each step in the dispensing process.

(k) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with this section.

(L) The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law.

History: CR 01-075: cr. Register November 2003 No. 575, eff. 12-1-03